

US3482005 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:44:17

All time stamps listed in this document are displayed in GMT

US3482005

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 21:57:09

Generated On: 09 Jun 2021 17:44:17

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[Participant ID](#)

US3482005

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

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US3482005

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:03:27

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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) 13 Feb 2021 15:03:27

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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) 13 Feb 2021 15:03:27

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Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Condition	SINUS SURGERY
Start date (dd MMM yyyy)	01 JAN 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JAN 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 15:03:27

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Condition	GASTRIC BYPASS
Start date (dd MMM yyyy)	01 JAN 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JAN 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 15:03:27

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Condition	DEVIATED SINUS SEPTUM
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 15:03:27

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Condition	MENOPAUSE
Start date (dd MMM yyyy)	01 JUN 2015
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)	JUN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:55 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 14:55
Height ( <i>xxx.x</i> )	62.5 in
Weight ( <i>xxx.x</i> )	233.2 lb
BMI ( <i>xxx.x</i> )	42.06088 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	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) 13 Feb 2021 15:03:27

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 15:03:27

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Date of assessment (*dd MMM yyyy*) 10 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) 01 JUN 2015

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:03:27

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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

FINANCE DEPARTMENT OF  
BUILDING MATERIALS  
WAREHOUSE

### 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) 13 Feb 2021 15:03:27

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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)	False
<b>Other</b>	True
<b>Specify</b>	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:03:27

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 15:03:27

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What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 143538

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Height	ND - Not Done
Weight	ND - Not Done



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

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)	10 AUG 2020
Time of assessment (00:00-23:59)	14:49 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 14:49
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	16:57 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 16:57
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 16:17 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 16:17

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

15:25 (24 HR)

Collection date and time (derived)

10 AUG 2020 15:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:33	10 AUG 2020 15:33
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 16:59

PC Open Date & Time

10 AUG 2020 16:37

PC Close Date & Time

10 AUG 2020 19:07



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**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 98.2 °F

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

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

PC Time Stamp	10 AUG 2020 20:38
PC Open Date & Time	10 AUG 2020 20:02
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 13:24

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 20:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 22:23

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 21:27

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 21:37

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 13:33

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**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

10 AUG 2020 17:00

PC Open Date & Time

10 AUG 2020 16:37

PC Close Date & Time

10 AUG 2020 19:07



US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**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

10 AUG 2020 20:38

PC Open Date & Time

10 AUG 2020 20:02

PC Close Date & Time

11 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**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

11 AUG 2020 13:25

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**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

12 AUG 2020 20:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**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

13 AUG 2020 22:24

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**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

14 AUG 2020 21:28

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**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

15 AUG 2020 21:38

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**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

16 AUG 2020 13:34

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**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 ☐



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 17:01
PC Open Date & Time	10 AUG 2020 16:37
PC Close Date & Time	10 AUG 2020 19:07

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**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 ☐

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 20:39
PC Open Date & Time	10 AUG 2020 20:02
PC Close Date & Time	11 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**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 ☒

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 13:26
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

53 of 3300

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:22
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 3300

EAB) (1725)



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 22:25
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 21:29
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

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 ☒

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:38
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 13:35
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3482005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3482005

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:03:46

Generated On: 09 Jun 2021 17:44:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:03:46

Generated On: 09 Jun 2021 17:44:17

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)	9 SEP 2020
Time of assessment (00:00-23:59)	10:12 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 10:12
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:03:46

Generated On: 09 Jun 2021 17:44:17

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 11:31
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



US3482005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:03:46

Generated On: 09 Jun 2021 17:44:17

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

9 SEP 2020

---

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

---

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 11:01 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 11:01

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

US3482005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	10:38 (24 HR)
Collection date and time (derived)	9 SEP 2020 10:38

US3482005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:42	9 SEP 2020 10:42
Nasopharyngeal Swab 2	No		

US3482005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:03:27

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 11:38

PC Open Date & Time

09 SEP 2020 11:21

PC Close Date & Time

09 SEP 2020 13:51

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	09 SEP 2020 21:54
PC Open Date & Time	09 SEP 2020 14:46
PC Close Date & Time	10 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**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

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

10 SEP 2020 21:26

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 12:05

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 22:34

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

13 SEP 2020 16:42

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

14 SEP 2020 12:09

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**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.

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:55

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 11:39

PC Open Date & Time

09 SEP 2020 11:21

PC Close Date & Time

09 SEP 2020 13:51

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**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

09 SEP 2020 21:53

PC Open Date & Time

09 SEP 2020 14:46

PC Close Date & Time

10 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**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

10 SEP 2020 21:26

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**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

11 SEP 2020 12:05

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**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

12 SEP 2020 22:33

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**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

13 SEP 2020 16:42

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**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

14 SEP 2020 12:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**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

15 SEP 2020 21:55

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**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 ☐

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 11:39
PC Open Date & Time	09 SEP 2020 11:21
PC Close Date & Time	09 SEP 2020 13:51

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**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 ☐



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 21:54
PC Open Date & Time	09 SEP 2020 14:46
PC Close Date & Time	10 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**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 ☒

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 21:27
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

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

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**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 ☒

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 22:33
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 16:43
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

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 ☒

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:11
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:56
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3482005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3482005

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:03:26

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:03:46

Generated On: 09 Jun 2021 17:44:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:03:46

Generated On: 09 Jun 2021 17:44:17

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

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

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3482005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:03:46

Generated On: 09 Jun 2021 17:44:17

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.*

US3482005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:03:46

Generated On: 09 Jun 2021 17:44:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	13:25 (24 HR)
Collection date and time (derived)	7 OCT 2020 13:25

US3482005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:03:46

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 18:40:10

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 OCT 2020 02:48:46

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 07:07:29

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 22:02:22

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 08:20:15

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 05:29:17

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**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

02 DEC 2020 06:47:41

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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	09 DEC 2020 12:43:32
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**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

16 DEC 2020 09:19:10

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 00:23:22

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 18:18:30
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 17:31:35

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 07:51:53

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 13:27:00

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 17:34:24

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 04:44:16

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 18:33:58
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 20:21:36
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 02:24:29

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 03:40:30

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 08:15:10

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 06:36:51

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

---

28 MAR 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 10:36:01

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 APR 2021 10:15:09
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 08:14:30

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 12:07:24

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAY 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	18 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	22 AUG 2021 23:59
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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 SEP 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 SEP 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2021 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59
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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59
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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 DEC 2021 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 FEB 2022 23:59



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 FEB 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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02 MAR 2022 00:01

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06 MAR 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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09 MAR 2022 00:01

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13 MAR 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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03 APR 2022 23:59



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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



US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUL 2022 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUL 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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24 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 AUG 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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14 SEP 2022 00:01

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18 SEP 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

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[Patient Cloud Open Date & Time](#)

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 OCT 2022 23:59

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US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59



US3482005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:44:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 03:40:54

US3482005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3482005

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

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

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3482005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

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.*

US3482005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 APR 2021
Collection time (00:00-23:59)	10:27 (24 HR)
Collection date and time (derived)	23 APR 2021 10:27

US3482005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 16:16:51

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 16:16:50

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 16:16:50

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3482005

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

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*

**US3482005**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:44:17**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 21:57:09

Generated On: 09 Jun 2021 17:44:17

Date of Contact	08 JAN 2021
Time of Contact	13:05
Date and Time of Contact (derived)	08 JAN 2021 13:05
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>

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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"/>

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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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US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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"/>



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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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US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input 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 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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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Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input 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 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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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Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input 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 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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	02 JAN 2021
------	-------------

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

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 checked="" type="checkbox"/>

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

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

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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	03 JAN 2021	
Assessment Not Done	False	
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 checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input 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 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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	04 JAN 2021	
Assessment Not Done	False	
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 checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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	05 JAN 2021	
Assessment Not Done	False	
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 checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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"/>



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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	06 JAN 2021	
Assessment Not Done	False	
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 checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input 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 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 JAN 2021	
Assessment Not Done	False	
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 checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	09 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	92 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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"/>

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 ☐

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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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Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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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Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

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 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

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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EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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"/>

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (22)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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"/>

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 JAN 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

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 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input checked="" type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (24)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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"/>

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input checked="" type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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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US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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"/>

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input checked="" 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 08 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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"/>

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input checked="" 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 08 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	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"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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 08 Jan 2021

Form: Symptom Log (28)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input checked="" 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 08 Jan 2021

Form: Symptom Log (28)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	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"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

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"/>

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 21:57:09

Generated On: 09 Jun 2021 17:44:17

Date of Visit	08 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	08 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

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 09 JAN 2021  
End Date 15 JAN 2021  
Oxygen Saturation 92 %

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 \_\_\_\_\_

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

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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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

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

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	Yes	12 JAN 2021
Day 7	Yes	14 JAN 2021
Day 9	Yes	16 JAN 2021
Day 14	Yes	21 JAN 2021
Day 21	Yes	28 JAN 2021
Day 28	Yes	04 FEB 2021



US3482005

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 JAN 2021
Time of assessment (00:00-23:59)	13:11 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 13:11
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482005

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 JAN 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3482005

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 JAN 2021

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 22:17:21

Generated On: 09 Jun 2021 17:44:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 22:17:21

Generated On: 09 Jun 2021 17:44:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 12:39
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:57:09

Generated On: 09 Jun 2021 17:44:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 FEB 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Mar 2021 22:17:21

Generated On: 09 Jun 2021 17:44:17

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

04 FEB 2021



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	04 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Date of updated informed consent ( <i>dd MMM yyyy</i> )	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	04 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 12:39
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	13:48 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 13:48
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

04 FEB 2021

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

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US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 04 FEB 2021

What was the treatment time? (00:00-23:59) 13:16 (24 HR)

Treatment Date and Time (derived) 04 FEB 2021 13:16

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

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 FEB 2021

Collection time (00:00-23:59)

12:16 (24 HR)

Collection date and time (derived)

04 FEB 2021 12:16



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	04 FEB 2021
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Collection time (00:00 - 23:59)	12:21
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Collection Date and Time (derived)	04 FEB 2021 12:21
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US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3482005

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

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)	12 MAR 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 08:55
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

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)	12 MAR 2021
Time of assessment (00:00-23:59)	10:29 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 10:29
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3482005

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

12 MAR 2021

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---



US3482005

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 MAR 2021

What was the treatment time? (00:00-23:59) 09:50 (24 HR)

Treatment Date and Time (derived) 12 MAR 2021 09:50

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3482005

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3482005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482005

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3482005

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3482005

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

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.*

US3482005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 APR 2021

Collection time (00:00-23:59)

10:27 (24 HR)

Collection date and time (derived)

23 APR 2021 10:27



US3482005

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:09:37

Generated On: 09 Jun 2021 17:44:17

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

AEID	USA-US106-2021-MRNA-1273-P30 1000006
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	26 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	THE STOP DATE OF SYMPTOMS IS 23JAN2021. WE HAVE UPDATED AFTER CLARIFYING WITH SUBJECT. THE ECRF IS ALSO UPDATED.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	

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**US3482005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed:** (b) (4) 23 Apr 2021 03:22:10

**Generated On: 09 Jun 2021 17:44:17**

---

Admitted to ICU Derived (CSA Programming Field Only)

---

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

AEID

Adverse event

BILATERAL LOWER  
EXTREMITY SWELLING (LEFT  
>RIGHT)

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)

05 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

---

PARTICIPANT WAS  
CONTACTED TODAY IN  
REGARDS TO SAFETY  
NOTIFICATION FROM EDIARY;  
SUBJECT WAS SEEN BY PCP  
FOR BILATERAL ANKLE AND  
FOOT SWELLING  
(LEFT>RIGHT). ONSET OF  
SWELLING BEGAN AT END OF  
DAY ON 4/5/21. PARTICIPANT  
WAS OUTSIDE GARDENING  
AND NOTICED SWELLING  
BEFORE BEDTIME.  
PARTICIPANT WAS SEEN BY  
PCP ON 4/8/21 AND WAS TOLD  
TO D/C GLIPIZIDE (CAN CAUSE  
LOWER EXTREMITY  
SWELLING), REDUCE  
AMLODIPINE TO 5MG BID PO,  
AND BEGIN  
HYDROCHLOROTHIAZIDE 12.5  
MG PO QAM IN ORDER TO  
REDUCE SWELLING OF LOWER  
EXTREMITIES. CHANGES TO  
MEDICATIONS WERE MADE  
4/9/21 AND PT. HAS NOT SEEN  
CHANGE IN SWELLING YET.  
PER PT., WAS NOT ADVISED TO  
WEAR COMPRESSION  
STOCKINGS OR ELEVATE LEGS  
HS BY PCP. DENIES ANY  
SIGNS/SYMPTOMS OF DVT.  
DENIES TRAUMA, SOB, OR  
CARDIAC EPISODES.  
PARTICIPANT WORKS IN

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 03:22:10

Generated On: 09 Jun 2021 17:44:17

---

ACCOUNTING AND SITS  
MOSTLY ALL DAY. NOTICES  
SWELLING TYPICALLY BEGINS  
MID-DAY AND WORSE HS.  
THEN, RESOLVES UPON  
AWAKENING AND RECURS QD.  
PARTICIPANT IS SCHEDULED  
TO F/U WITH PCP 5/7/21.  
AGREES TO UPDATE WITH  
CHANGES.  
ADDENDUM: DENIES PITTING  
IN LOWER EXTREMITIES.

---

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)	

---

---



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 22:17:21

Generated On: 09 Jun 2021 17:44:17

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	UNK
Dose per administration	UNK
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNK
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 18:20:37

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Name of Medication PIOGLITAZONE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 15

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) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication TRIAMTERENE/HYDROCHLORO  
THIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HIGH BLOOD PRESSURE

Dose per administration 37.5/25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JAN 2021
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 (4)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 400

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☒  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication BAYER ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication UNKNOWN

Dose per administration 325

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication LUMIGAN  
COMBIGAN  
TIMOLOL  
(BRIMONIDINE/TIMOLOL)  
(BIMATOPROST)

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL GLAUCOMA

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 18:20:37

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	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input checked="" type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ULCER

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 18:20:37

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	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) _____		
Start date completely unknown		True
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 (8)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 APR 2021
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 (9)

Data signed: (b) (4) 28 Apr 2021 18:20:37

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Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HIGH BLOOD PRESSURE

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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) _____		
Start date completely unknown		True
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 (10)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication BIOTIN

Prophylaxis Yes ☐  
No ☒

Indication NUTRITIONAL 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 (10)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (13)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication ATROVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 80

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 (13)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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) _____		
Start date completely unknown		True
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 (14)

Data signed: (b) (4) 28 Apr 2021 18:20:37

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Name of Medication FLUTICASONE

Prophylaxis Yes ☒  
No ☐

Indication UNKNOWN

Dose per administration 50

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication ZICAM (OXYMETAZOLINE NASAL)

Prophylaxis Yes ☒  
No ☐

Indication UNKNOWN

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

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 (15)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE

Dose per administration 0.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication ZICAM (OXYMETAZOLINE NASAL)

Prophylaxis Yes ☐  
No ☒

Indication RUNNY NOSE

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

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 (17)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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)		27 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication AIRBORNE

Prophylaxis Yes ☒  
No ☐

Indication IMMUNE SUPPORT

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

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 (18)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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)		27 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 DEC 2020		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication THERAFLU(ACETAMINOPHEN,  
DEXTROMETHORPHAN HBR,  
PHENYLEPHRINE HCL)

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

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 (19)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	27 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication HYDROMET

Prophylaxis Yes ☐  
No ☒

Indication RUNNY NOSE

Dose per administration 2.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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)	27 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HIGH BLOOD PRESSURE

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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 JAN 2021	
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 (22)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication OZEMPIC

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 0.5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☒  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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)	13 JAN 2021	
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 checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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 2016	
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)	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 (24)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication LEG SWELLING

Dose per administration 25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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)	08 APR 2021	
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"/>

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 18:20:37

Generated On: 09 Jun 2021 17:44:17

	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)	08 APR 2021	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3482005

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 22:17:21

Generated On: 09 Jun 2021 17:44:17

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---



US3482005

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:44:17

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3482005

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:44:17

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

SAEID	USA-US106-2021-MRNA-1273-P301000006
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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

SAEID	USA-US106-2021-MRNA-1273-P301000006
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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/JAN/2021 18:30
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

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

SAEID	USA-US106-2021-MRNA-1273-P301000006
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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/FEB/2021 14:27
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

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 21:57:11

Generated On: 09 Jun 2021 17:44:17

SAEID	USA-US106-2021-MRNA-1273-P301000006
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	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/MAR/2021 16:57
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

US3482005 (Prod: Hope Clinic of The Emory Vaccine Center)

**US3482005**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:44:17**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'US3482005'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:39:18



US3482005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	10 Aug 2020 20:48:48

US3482005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:39:19

US3482005

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Clinic (Clinic)'	(b) (4) Hollie Macenczak (b) (4)	10 Aug 2020 20:48:48

**US3482005**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:44:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'SCRN'	System	10 Aug 2020 20:48:48

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:39:20

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered '57'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

**US3482005**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:44:17**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'YEARS'	System	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered '57'	System	10 Aug 2020 20:49:12



US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered 'Female (F)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered '0'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered 'l'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered '0'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered '0'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered '0'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered '0'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05



US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered empty.	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered '0'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:44:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:33
User entered '0'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:05

US3482005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:10
User entered '10 Aug 2020'	Hollie Macenczak (b) (4)	10 Aug 2020 20:49:12

**US3482005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:44:17**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'Aug 2020'	System	10 Aug 2020 20:49:12

**US3482005**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:44:17**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered '2020'	System	10 Aug 2020 20:49:12

US3482005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Amendment 2 dated 31Jul2020 was approved at your site on 06Aug2020 and the approval notice was dated 10Aug2020. Please confirm and update to Amendment 2.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:41:00
Query 'Amendment 2 dated 31Jul2020 was approved at your site on 06Aug2020 and the approval notice was dated 10Aug2020. Please confirm and update to Amendment 2.' answered with 'Amendment 1 is correct as written' (Site from CRA).	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:12:41
User opened query 'Amendment 2 dated 31Jul2020 was approved at your site on 06Aug2020 and the approval notice was dated 10Aug2020. Please confirm and update to Amendment 2.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:20:34
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:41:10
Query 'Per source, patient was consented under Amendment 2 Informed consent approved on 06Aug2020. Please confirm and update.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:49:03
User opened query 'Per source, patient was consented under Amendment 2 Informed consent approved on 06Aug2020. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 16:15:02
User entered 'Amendment 1 (1)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:49:12

US3482005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:17

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:10
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:49:12



US3482005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:17

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:10
User entered empty.	Hollie Macenczak (b) (4)	10 Aug 2020 20:49:12

US3482005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:10
User entered empty.	Hollie Macenczak (b) (4)	10 Aug 2020 20:49:12

US3482005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:10
User entered 'No (N)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:49:12

US3482005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:10
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:39:19

US3482005

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:44:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'I'	System	10 Aug 2020 20:51:12

US3482005

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:44:17

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:45
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:51:12

US3482005

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:44:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:08:04

US3482005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 18:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:15:19
Data point term sent to Coder	System	11 Aug 2020 18:13:45
User entered 'Diabetes mellitus Type 2'	(b) (4), (b) (6)	11 Aug 2020 18:13:06



US3482005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:06

US3482005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:06

US3482005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:06

US3482005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:06

US3482005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:06

**US3482005**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:44:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:13:06

US3482005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:13:06

US3482005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:13:06



US3482005

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:44:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:13:06

US3482005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 18:15:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:15:17
Data point term sent to Coder	System	11 Aug 2020 18:13:45
User entered 'Hypertension'	(b) (4), (b) (6)	11 Aug 2020 18:13:19

US3482005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:19

US3482005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:19

US3482005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:19

US3482005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:19

US3482005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:13:19

US3482005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:13:19



US3482005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:13:19

**US3482005**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:13:19

US3482005

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:44:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:13:19

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Per DM CLR: Please specify the location and/or type of ULCER (e.g. peptic, duodenal, esophageal, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:16:42
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastrointestinal ulcers and perforation, site unspecified, PT: Gastrointestinal ulcer, LLT: Gastrointestinal ulcer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 07:46:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 07:46:51
Data point term sent to Coder	System	29 Sep 2020 13:23:34
Query 'Per DM CLR: Please specify the location and/or type of ULCER (e.g. peptic, duodenal, esophageal, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Participant was told it was an upper GI ulcer and she has no additional info' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:23:28
Coding entries removed.	(b) (4), (b) (6)	29 Sep 2020 13:23:08
User entered 'UPPER GI ULCER' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Sep 2020 13:23:08
User opened query 'Per DM CLR: Please specify the location and/or type of ULCER (e.g. peptic, duodenal, esophageal, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 20:26:22

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

Condition

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Ulcers NEC, PT: Ulcer, LLT: Ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:16:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:16:10
Data point term sent to Coder	System	11 Aug 2020 18:14:52
User entered 'Ulcer'	(b) (4), (b) (6)	11 Aug 2020 18:14:42

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:14:42

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:14:42

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 18:15:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:15:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 18:14:42
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:14:42



US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:14:42

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:15:36
User entered '1'		11 Aug 2020 18:14:42

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:14:42

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:14:42

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:14:42

US3482005

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:44:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:14:42

US3482005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:16:49
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma both eyes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:24:59
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 13:24:59
Data point term sent to Coder	System	29 Sep 2020 13:24:35
Query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:24:23
Coding entries removed.		29 Sep 2020 13:24:18
User entered 'BILATERAL GLAUCOMA' reason for change: Per Query Resolution		29 Sep 2020 13:24:18
User opened query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		23 Sep 2020 20:26:39
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:17:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:17:14

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:17

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Aug 2020 18:15:53
User entered 'Glaucoma'	(b) (4), (b) (6)	11 Aug 2020 18:15:07



US3482005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:15:07

US3482005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:15:07

US3482005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:15:07

US3482005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:15:07

US3482005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:15:07

US3482005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:15:07

US3482005

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:44:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:15:07

**US3482005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:44:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:15:07



**US3482005**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:44:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:15:07

US3482005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 18:18:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:18:15
Data point term sent to Coder	System	11 Aug 2020 18:16:56
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	11 Aug 2020 18:16:10

US3482005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:16:10

US3482005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:16:10

US3482005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:16:10

US3482005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:16:10

US3482005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:16:10

**US3482005**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:44:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:16:10



US3482005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:16:10

US3482005

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:44:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:16:10

**US3482005**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:44:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	11 Aug 2020 18:16:10

US3482005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 19:16:23
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Added associated condition' (Site from DM).		29 Sep 2020 13:26:40
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).		23 Sep 2020 20:27:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:19:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:19:18
Data point term sent to Coder	System	11 Aug 2020 18:17:58
User entered 'Sinus surgery'	(b) (4), (b) (6)	11 Aug 2020 18:17:40

US3482005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '01 Jan 1995'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:17:40

US3482005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:17:40

US3482005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:17:40

US3482005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '01 Jan 1995'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:17:40



US3482005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:17:40

**US3482005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:44:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'Jan 1995'	System	11 Aug 2020 18:17:40

US3482005

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:44:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered '1995'	System	11 Aug 2020 18:17:40

**US3482005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:44:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'Jan 1995'	System	11 Aug 2020 18:17:40

**US3482005**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:44:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered '1995'	System	11 Aug 2020 18:17:40

US3482005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:44:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 18:20:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:20:20
Data point term sent to Coder	System	11 Aug 2020 18:19:00
User entered 'Gastric bypass'	(b) (4), (b) (6)	11 Aug 2020 18:18:06

US3482005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:44:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '01 Jan 2009'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:18:06

US3482005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:18:06



US3482005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:44:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:18:06

US3482005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:44:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '01 Jan 2009'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:18:06

US3482005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:44:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:18:06

**US3482005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:44:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'Jan 2009'	System	11 Aug 2020 18:18:06

**US3482005**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:44:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered '2009'	System	11 Aug 2020 18:18:06

US3482005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:44:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'Jan 2009'	System	11 Aug 2020 18:18:06

US3482005

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:44:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered '2009'	System	11 Aug 2020 18:18:06

US3482005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:44:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Sep 2020 15:20:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:20:39
Data point term sent to Coder	System	29 Sep 2020 13:27:38
User entered 'DEVIATED SINUS SEPTUM'	(b) (4), (b) (6)	29 Sep 2020 13:27:31



US3482005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:44:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:27:31

US3482005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:27:31

US3482005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:44:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:27:31

US3482005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:44:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'UN UNK 1995'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:27:31

US3482005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:44:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:27:31

**US3482005**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:44:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	29 Sep 2020 13:27:31

US3482005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:44:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	29 Sep 2020 13:27:31

US3482005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:44:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'Jan 1995'	System	29 Sep 2020 13:27:31



US3482005

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:44:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered '1995'	System	29 Sep 2020 13:27:31

US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:32:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:32:29
Data point term sent to Coder	System	23 Oct 2020 15:31:59
User entered 'menopause'	Michele McCullough (b) (4)	23 Oct 2020 15:31:26

US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '01 Jun 2015'	Michele McCullough (b) (4)	23 Oct 2020 15:31:26

US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	Michele McCullough (b) (4)	23 Oct 2020 15:31:26

US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	Michele McCullough (b) (4)	23 Oct 2020 15:31:26

US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) Michele McCullough	23 Oct 2020 15:31:26
	(b) (4)	

US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	Michele McCullough (b) (4)	23 Oct 2020 15:31:26

US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'Jun 2015'	System	23 Oct 2020 15:31:26



US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered '2015'	System	23 Oct 2020 15:31:26

US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	23 Oct 2020 15:31:26

US3482005

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:44:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered empty.	System	23 Oct 2020 15:31:26

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:43:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:43:57
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:43:57
User entered '14:55'	(b) (4), (b) (6)	11 Aug 2020 18:09:10

**US3482005**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered '10 Aug 2020 14:55'	System	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:45
User entered '62.5' in	(b) (4), (b) (6)	11 Aug 2020 18:09:10
DataPoint set to visible.	System	10 Aug 2020 20:51:12



US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:49
User entered '233.2' lb	(b) (4), (b) (6)	11 Aug 2020 18:09:10
DataPoint set to visible.	System	10 Aug 2020 20:51:12

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
Amendment Manager: User entered '42.06088'	System	16 Sep 2020 23:50:23
User entered '42.1'	System	11 Aug 2020 18:09:10
DataPoint set to visible.	System	10 Aug 2020 20:51:12

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'kg/m2'	System	11 Aug 2020 18:09:10
DataPoint set to visible.	System	10 Aug 2020 20:51:12

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:57
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:42:57
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:31:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 15:31:23
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 19:29:53
User entered '98.8' F	(b) (4), (b) (6)	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:57
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 15:31:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:43:57
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 15:31:23
User entered '88'	(b) (4), (b) (6)	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'bpm'	System	11 Aug 2020 18:09:10



US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:57
User entered missing code ND - Not Done; reason for change Per Query Resolution		22 Sep 2020 15:31:23
User entered '20'		11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'breaths/min'	System	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:57
User entered missing code ND - Not Done; reason for change Per Query Resolution		22 Sep 2020 15:31:23
User entered '148'		11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'mmHg'	System	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:57
User entered missing code ND - Not Done; reason for change Per Query Resolution		22 Sep 2020 15:31:23
User entered '73'		11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User entered 'mmHg'	System	11 Aug 2020 18:09:10

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09

US3482005

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09



US3482005

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:09:18

US3482005

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 09:26:53
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 14:56:29
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:09:18

US3482005

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:09:50

US3482005

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:17

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:09:50

US3482005

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:17

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query ' Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 22:29:47
Query ' Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate' answered with 'It is listed in MH #9' (Site from DM).		23 Nov 2020 21:24:37
User opened query ' Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate' (Site from DM).		13 Nov 2020 09:13:02
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).		13 Nov 2020 04:26:49
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'Menopause is not a medical condition' (Site from DM).		20 Oct 2020 18:43:16
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).		09 Oct 2020 05:26:39
User entered 'Post-menopausal (POST-MENOPAUSAL)'		11 Aug 2020 18:09:50

US3482005

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:17

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:09:50

US3482005

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:17

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:09:50

US3482005

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:17

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:09:50



US3482005

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:17

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '01 Jun 2015'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:09:50

US3482005

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:44:17

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:09:50

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

[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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06



US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

[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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'No (N)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'Yes (Y)'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered 'Finance department of building materials warehouse'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	10 Feb 2021 20:52:25
User entered '0' reason for change: Data Entry Error	System	10 Feb 2021 20:52:25
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Feb 2021 20:52:16
User entered '1'	System	11 Aug 2020 18:12:06



US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**Resides in Nursing Home or Assisted Living Facility**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered '0'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered '0'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

**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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered '0'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

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 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered '0'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User closed query 'Per source, patient Resides in a community with ongoing person to person transmission.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:56:06
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
Query 'Per source, patient Resides in a community with ongoing person to person transmission.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:52:43
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:50:31
User opened query 'Per source, patient Resides in a community with ongoing person to person transmission.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 21:50:25
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 20:52:16
User entered '0'		11 Aug 2020 18:12:06

US3482005

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:44:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:36:09
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:56:13
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 20:52:16
User entered 'resident in a community with ongoing person to person transmission.' reason for change:	(b) (4), (b) (6)	10 Feb 2021 20:52:16
Data Entry Error	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:50:31
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:12:06

US3482005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	10 Aug 2020 20:49:33



US3482005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10 Aug 2020'	(b) (4) Hollie Macenczak (b) (4)	10 Aug 2020 20:49:33

US3482005

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Home (Home)'	(b) (4) Hollie Macenczak (b) (4)	10 Aug 2020 20:49:33

**US3482005**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:44:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'VISIT1'	System	10 Aug 2020 20:49:33

US3482005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:17

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:46:48
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:54:27

US3482005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:17

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:46:48
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:22:16
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:22:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 19:54:27
User entered '143538' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:54:27

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:17

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:46:48
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:54:27

US3482005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:17

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)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:46:48
User entered 'No (N)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:50:19

US3482005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:17

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)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:46:48
User entered 'No (N)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:50:19



US3482005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:17

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:46:48
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:50:19

US3482005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:46:48
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:50:19

US3482005

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:44:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:46:48
User entered 'No (N)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:50:19

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:29:07
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'Updated' (Site from DM).		22 Sep 2020 15:32:20
User entered missing code ND - Not Done; reason for change Per Query Resolution		22 Sep 2020 15:32:12
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).		18 Sep 2020 19:29:42
User entered '62.5' in		11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Per CDM: Per previous query above, please record weight as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:52:22
Query 'Per CDM: Per previous query above, please record weight as Not Done.' answered with 'Updated' (Site from DM).		24 Sep 2020 20:16:00
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 20:15:49
User opened query 'Per CDM: Per previous query above, please record weight as Not Done.' (Site from DM).		24 Sep 2020 13:29:43
User entered empty; reason for change Per Query Resolution		22 Sep 2020 15:32:12
User entered '233.2' lb		11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:29:07
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'Updated' (Site from DM).		22 Sep 2020 15:32:20
User entered missing code ND - Not Done; reason for change Per Query Resolution		22 Sep 2020 15:32:12
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).		18 Sep 2020 19:29:42
User entered '62.5' in		11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Per CDM: Per previous query above, please record weight as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:52:22
Query 'Per CDM: Per previous query above, please record weight as Not Done.' answered with 'Updated' (Site from DM).		24 Sep 2020 20:16:00
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 20:15:49
User opened query 'Per CDM: Per previous query above, please record weight as Not Done.' (Site from DM).		24 Sep 2020 13:29:43
User entered empty; reason for change Per Query Resolution		22 Sep 2020 15:32:12
User entered '233.2' lb		11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User accepted default value 'Pre-Dose (PREDOSE)'		11 Aug 2020 18:02:13



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '14:49'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:02:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered '10 Aug 2020 14:49'	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:03:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:03:39
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:03:39
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:03:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	System	11 Aug 2020 18:03:39
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 18:02:13
User entered empty.	System	11 Aug 2020 18:02:13
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:03:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:03:39
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:03:39
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'bpm'	System	11 Aug 2020 18:03:39
User entered empty.	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:03:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:03:39
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:03:39
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'breaths/min'	System	11 Aug 2020 18:03:39
User entered empty.	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:03:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:03:39
User entered '148' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:03:39
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'mmHg'	System	11 Aug 2020 18:03:39
User entered empty.	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:03:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:03:39
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:03:39
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'mmHg'	System	11 Aug 2020 18:03:39
User entered empty.	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 13:29:07
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:32:20
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 15:32:12
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 19:29:42
User entered '62.5' in	(b) (4), (b) (6)	11 Aug 2020 18:02:13



US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Per CDM: Per previous query above, please record weight as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:52:22
Query 'Per CDM: Per previous query above, please record weight as Not Done.' answered with 'Updated' (Site from DM).		24 Sep 2020 20:16:00
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 20:15:49
User opened query 'Per CDM: Per previous query above, please record weight as Not Done.' (Site from DM).		24 Sep 2020 13:29:43
User entered empty; reason for change Per Query Resolution		22 Sep 2020 15:32:12
User entered '233.2' lb		11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Aug 2020 18:02:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:02:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 12:17:37
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 18:02:13
User entered '16:57'	(b) (4), (b) (6)	11 Aug 2020 18:02:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered '10 Aug 2020 16:57'	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:04:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:04:57
User entered '97.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:04:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:04:57
User entered 'Oral (Oral)' reason for change: Data Entry Error	System	11 Aug 2020 18:04:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 18:02:13
User entered empty.	System	11 Aug 2020 18:02:13
	(b) (4), (b) (6)	11 Aug 2020 18:02:13



US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:04:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:04:57
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:04:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'bpm'	System	11 Aug 2020 18:04:57
User entered empty.	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:04:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:04:57
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:04:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'breaths/min'	System	11 Aug 2020 18:04:57
User entered empty.	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:04:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:04:57
User entered '150' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:04:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'mmHg'	System	11 Aug 2020 18:04:57
User entered empty.	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 18:04:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 18:04:57
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 18:04:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 18:02:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:02:13



US3482005

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'mmHg'	System	11 Aug 2020 18:04:57
User entered empty.	System	11 Aug 2020 18:02:13

US3482005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:05:49

US3482005

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:05:49

US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:44:46
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:52:04

US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:44:46
User entered empty.	Hollie Macenczak (b) (4)	10 Aug 2020 20:52:04

US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

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)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:44:46
User entered empty.	Hollie Macenczak (b) (4)	10 Aug 2020 20:52:04

US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 20:52:04

US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:44:46
User entered '10 Aug 2020'	Hollie Macenczak (b) (4)	10 Aug 2020 20:52:04



US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:44:46
User entered '16:17'	Hollie Macenczak (b) (4)	10 Aug 2020 20:52:04

US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered '10 Aug 2020 16:17'	System	10 Aug 2020 20:52:04

US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:44:46
User entered 'Left Arm (LEFT ARM)'	Hollie Macenczak (b) (4)	10 Aug 2020 20:52:04

US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:44:46
User entered 'ONCE'	System	10 Aug 2020 20:52:04

US3482005

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 20:52:04

US3482005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:06:38

US3482005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:06:38

US3482005

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '15:25'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:06:38



**US3482005**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:44:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered '10 Aug 2020 15:25'	System	11 Aug 2020 18:06:38

US3482005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:44:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:07:07

US3482005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Aug 2020 18:07:07

US3482005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:07:07

US3482005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '15:33'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:07:07

US3482005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered '10 Aug 2020 15:33'	System	11 Aug 2020 18:07:07

US3482005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Aug 2020 18:07:07

US3482005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:07:07



US3482005

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:07:07

**US3482005**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered empty.	System	11 Aug 2020 18:07:07

US3482005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 18:07:13

US3482005

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'I'	System	11 Aug 2020 18:07:13

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T16:57:57', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e013ac5a-e39a-4ea1-b077-71c4e2795192'	System	10 Aug 2020 20:59:18
User entered 'Yes (Y)'	System	10 Aug 2020 20:59:18

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T16:58:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e013ac5a-e39a-4ea1-b077-71c4e2795192'	System	10 Aug 2020 20:59:18
User entered '97.1'	System	10 Aug 2020 20:59:18

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T16:58:41', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e013ac5a-e39a-4ea1-b077-71c4e2795192'	System	10 Aug 2020 20:59:18
User entered 'No (N)'	System	10 Aug 2020 20:59:18



US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T16:59:13', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e013ac5a-e39a-4ea1-b077-71c4e2795192'	System	10 Aug 2020 20:59:18
User entered '10 Aug 2020 16:59'	System	10 Aug 2020 20:59:18

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Aug 2020 16:37'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Aug 2020 19:07'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:38:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e20de5c1-7171-4ec0-b98a-233bd39e6547'	System	11 Aug 2020 00:38:56
User entered 'Yes (Y)'	System	11 Aug 2020 00:38:56

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:38:42', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e20de5c1-7171-4ec0-b98a-233bd39e6547'	System	11 Aug 2020 00:38:56
User entered '98.2'	System	11 Aug 2020 00:38:56

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:38:48', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e20de5c1-7171-4ec0-b98a-233bd39e6547'	System	11 Aug 2020 00:38:56
User entered 'No (N)'	System	11 Aug 2020 00:38:56

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:38:52', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e20de5c1-7171-4ec0-b98a-233bd39e6547'	System	11 Aug 2020 00:38:56
User entered '10 Aug 2020 20:38'	System	11 Aug 2020 00:38:56



US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Aug 2020 20:02'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 2'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:24:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fee3effd-c6db-4f6a-bc5b-ef6205c1d5a3'	System	11 Aug 2020 17:24:32
User entered 'Yes (Y)'	System	11 Aug 2020 17:24:32

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:24:18', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fee3effd-c6db-4f6a-bc5b-ef6205c1d5a3'	System	11 Aug 2020 17:24:32
User entered '98.0'	System	11 Aug 2020 17:24:32

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:24:24', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fee3effd-c6db-4f6a-bc5b-ef6205c1d5a3'	System	11 Aug 2020 17:24:32
User entered 'No (N)'	System	11 Aug 2020 17:24:32

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:24:29', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fee3effd-c6db-4f6a-bc5b-ef6205c1d5a3'	System	11 Aug 2020 17:24:32
User entered '11 Aug 2020 13:24'	System	11 Aug 2020 17:24:32

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:52:04



US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 3'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:20:54', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ab93720d-bee1-43b4-87bc-95b4a5c6a983'	System	13 Aug 2020 00:21:20
User entered 'Yes (Y)'	System	13 Aug 2020 00:21:20

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:21:01', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ab93720d-bee1-43b4-87bc-95b4a5c6a983'	System	13 Aug 2020 00:21:20
User entered '98.6'	System	13 Aug 2020 00:21:20

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:21:08', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ab93720d-bee1-43b4-87bc-95b4a5c6a983'	System	13 Aug 2020 00:21:20
User entered 'No (N)'	System	13 Aug 2020 00:21:20

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:21:17', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ab93720d-bee1-43b4-87bc-95b4a5c6a983'	System	13 Aug 2020 00:21:20
User entered '12 Aug 2020 20:21'	System	13 Aug 2020 00:21:20

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:52:04



US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 4'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:23:27', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'cba50e64-ca6a-4fb7-ac62-007a053dfb5b'	System	14 Aug 2020 02:23:49
User entered 'Yes (Y)'	System	14 Aug 2020 02:23:49

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:23:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'cba50e64-ca6a-4fb7-ac62-007a053dfb5b'	System	14 Aug 2020 02:23:49
User entered '98.8'	System	14 Aug 2020 02:23:49

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:23:40', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'cba50e64-ca6a-4fb7-ac62-007a053dfb5b'	System	14 Aug 2020 02:23:49
User entered 'No (N)'	System	14 Aug 2020 02:23:49

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:23:46', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'cba50e64-ca6a-4fb7-ac62-007a053dfb5b'	System	14 Aug 2020 02:23:49
User entered '13 Aug 2020 22:23'	System	14 Aug 2020 02:23:49

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 5'	System	10 Aug 2020 20:52:04



US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:27:26', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fefa5d01-2c69-4cae-84db-c46f690332fc'	System	15 Aug 2020 01:27:53
User entered 'Yes (Y)'	System	15 Aug 2020 01:27:53

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:27:40', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fefa5d01-2c69-4cae-84db-c46f690332fc'	System	15 Aug 2020 01:27:53
User entered '97.4'	System	15 Aug 2020 01:27:53

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:27:46', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fefa5d01-2c69-4cae-84db-c46f690332fc'	System	15 Aug 2020 01:27:53
User entered 'No (N)'	System	15 Aug 2020 01:27:53

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:27:51', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fefa5d01-2c69-4cae-84db-c46f690332fc'	System	15 Aug 2020 01:27:53
User entered '14 Aug 2020 21:27'	System	15 Aug 2020 01:27:53

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 6'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:36:51', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '81c89ba5-e2c7-490b-924d-1075793844fb'	System	16 Aug 2020 01:37:13
User entered 'Yes (Y)'	System	16 Aug 2020 01:37:13



US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:36:57', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '81c89ba5-e2c7-490b-924d-1075793844fb' User entered '97.2'	System	16 Aug 2020 01:37:13
	System	16 Aug 2020 01:37:13

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:37:03', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '81c89ba5-e2c7-490b-924d-1075793844fb'	System	16 Aug 2020 01:37:13
User entered 'No (N)'	System	16 Aug 2020 01:37:13

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:37:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '81c89ba5-e2c7-490b-924d-1075793844fb'	System	16 Aug 2020 01:37:13
User entered '15 Aug 2020 21:37'	System	16 Aug 2020 01:37:13

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 7'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:33:36', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aadc3bb-adbc-429d-be3d-d8bdc39c99a8'	System	16 Aug 2020 17:33:58
User entered 'Yes (Y)'	System	16 Aug 2020 17:33:58

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:33:44', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aadc3bb-adbc-429d-be3d-d8bdc39c99a8'	System	16 Aug 2020 17:33:58
User entered '97.1'	System	16 Aug 2020 17:33:58



US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:33:48', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aadc3bb-adbc-429d-be3d-d8bdc39c99a8'	System	16 Aug 2020 17:33:58
User entered 'No (N)'	System	16 Aug 2020 17:33:58

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:33:55', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aadc3bb-adbc-429d-be3d-d8bdc39c99a8'	System	16 Aug 2020 17:33:58
User entered '16 Aug 2020 13:33'	System	16 Aug 2020 17:33:58

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:00:06', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '90473d87-684f-4bb9-b504-0e37c8d5946f'	System	10 Aug 2020 21:00:45
User entered 'None (1)'	System	10 Aug 2020 21:00:45

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:00:13', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '90473d87-684f-4bb9-b504-0e37c8d5946f'	System	10 Aug 2020 21:00:45
User entered 'No (N)'	System	10 Aug 2020 21:00:45

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:00:18', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '90473d87-684f-4bb9-b504-0e37c8d5946f'	System	10 Aug 2020 21:00:45
User entered 'No (N)'	System	10 Aug 2020 21:00:45



US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:00:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '90473d87-684f-4bb9-b504-0e37c8d5946f'	System	10 Aug 2020 21:00:45
User entered 'None (1)'	System	10 Aug 2020 21:00:45

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:00:42', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '90473d87-684f-4bb9-b504-0e37c8d5946f'	System	10 Aug 2020 21:00:45
User entered '10 Aug 2020 17:00'	System	10 Aug 2020 21:00:45

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Aug 2020 16:37'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Aug 2020 19:07'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:37:38', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '8c51a03c-ef16-40e8-92d7-fbe479825c66'	System	11 Aug 2020 00:38:19
User entered 'None (1)'	System	11 Aug 2020 00:38:19

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:37:44', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '8c51a03c-ef16-40e8-92d7-fbe479825c66'	System	11 Aug 2020 00:38:19
User entered 'No (N)'	System	11 Aug 2020 00:38:19

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:37:49', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '8c51a03c-ef16-40e8-92d7-fbe479825c66'	System	11 Aug 2020 00:38:19
User entered 'No (N)'	System	11 Aug 2020 00:38:19



US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:38:00', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '8c51a03c-ef16-40e8-92d7-fbe479825c66'	System	11 Aug 2020 00:38:19
User entered 'None (1)'	System	11 Aug 2020 00:38:19

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:38:05', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '8c51a03c-ef16-40e8-92d7-fbe479825c66'	System	11 Aug 2020 00:38:19
User entered '10 Aug 2020 20:38'	System	11 Aug 2020 00:38:19

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Aug 2020 20:02'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 2'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:24:55', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '4d5144dc-9158-4e9c-8c2f-da054c748495'	System	11 Aug 2020 17:25:27
User entered 'None (1)'	System	11 Aug 2020 17:25:27

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:24:59', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '4d5144dc-9158-4e9c-8c2f-da054c748495'	System	11 Aug 2020 17:25:27
User entered 'No (N)'	System	11 Aug 2020 17:25:27

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:25:04', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '4d5144dc-9158-4e9c-8c2f-da054c748495'	System	11 Aug 2020 17:25:27
User entered 'No (N)'	System	11 Aug 2020 17:25:27



US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:25:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '4d5144dc-9158-4e9c-8c2f-da054c748495'	System	11 Aug 2020 17:25:27
User entered 'None (1)'	System	11 Aug 2020 17:25:27

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:25:23', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '4d5144dc-9158-4e9c-8c2f-da054c748495'	System	11 Aug 2020 17:25:27
User entered '11 Aug 2020 13:25'	System	11 Aug 2020 17:25:27

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 3'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:21:25', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1f5d8c6d-d3d3-46dd-abf6-4ad4b8e28338'	System	13 Aug 2020 00:21:55
User entered 'None (1)'	System	13 Aug 2020 00:21:55

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:21:30', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1f5d8c6d-d3d3-46dd-abf6-4ad4b8e28338'	System	13 Aug 2020 00:21:55
User entered 'No (N)'	System	13 Aug 2020 00:21:55

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:21:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1f5d8c6d-d3d3-46dd-abf6-4ad4b8e28338'	System	13 Aug 2020 00:21:55
User entered 'No (N)'	System	13 Aug 2020 00:21:55



US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:21:45', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1f5d8c6d-d3d3-46dd-abf6-4ad4b8e28338'	System	13 Aug 2020 00:21:55
User entered 'None (1)'	System	13 Aug 2020 00:21:55

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:21:50', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1f5d8c6d-d3d3-46dd-abf6-4ad4b8e28338'	System	13 Aug 2020 00:21:55
User entered '12 Aug 2020 20:21'	System	13 Aug 2020 00:21:55

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 4'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:23:54', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a033ef74-774a-46e7-a9aa-fe504faff97d'	System	14 Aug 2020 02:24:25
User entered 'None (1)'	System	14 Aug 2020 02:24:25

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:23:58', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a033ef74-774a-46e7-a9aa-fe504faff97d'	System	14 Aug 2020 02:24:25
User entered 'No (N)'	System	14 Aug 2020 02:24:25

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:04', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a033ef74-774a-46e7-a9aa-fe504faff97d'	System	14 Aug 2020 02:24:25
User entered 'No (N)'	System	14 Aug 2020 02:24:25



US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a033ef74-774a-46e7-a9aa-fe504faff97d'	System	14 Aug 2020 02:24:25
User entered 'None (1)'	System	14 Aug 2020 02:24:25

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:24', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a033ef74-774a-46e7-a9aa-fe504faff97d'	System	14 Aug 2020 02:24:25
User entered '13 Aug 2020 22:24'	System	14 Aug 2020 02:24:25

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 5'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:27:59', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9a429d35-8302-466d-9e94-8d352b75be9f'	System	15 Aug 2020 01:28:22
User entered 'None (1)'	System	15 Aug 2020 01:28:22

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:04', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9a429d35-8302-466d-9e94-8d352b75be9f'	System	15 Aug 2020 01:28:22
User entered 'No (N)'	System	15 Aug 2020 01:28:22

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:08', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9a429d35-8302-466d-9e94-8d352b75be9f'	System	15 Aug 2020 01:28:22
User entered 'No (N)'	System	15 Aug 2020 01:28:22



US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:13', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9a429d35-8302-466d-9e94-8d352b75be9f'	System	15 Aug 2020 01:28:22
User entered 'None (1)'	System	15 Aug 2020 01:28:22

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:21', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9a429d35-8302-466d-9e94-8d352b75be9f'	System	15 Aug 2020 01:28:22
User entered '14 Aug 2020 21:28'	System	15 Aug 2020 01:28:22

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 6'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:37:16', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2c45b903-78f3-45ad-8183-a464cd6ca244'	System	16 Aug 2020 01:38:05
User entered 'None (1)'	System	16 Aug 2020 01:38:05

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:37:21', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2c45b903-78f3-45ad-8183-a464cd6ca244'	System	16 Aug 2020 01:38:05
User entered 'No (N)'	System	16 Aug 2020 01:38:05

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:37:26', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2c45b903-78f3-45ad-8183-a464cd6ca244'	System	16 Aug 2020 01:38:05
User entered 'No (N)'	System	16 Aug 2020 01:38:05



US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:37:51', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2c45b903-78f3-45ad-8183-a464cd6ca244'	System	16 Aug 2020 01:38:05
User entered 'None (1)'	System	16 Aug 2020 01:38:05

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:38:01', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2c45b903-78f3-45ad-8183-a464cd6ca244'	System	16 Aug 2020 01:38:05
User entered '15 Aug 2020 21:38'	System	16 Aug 2020 01:38:05

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 7'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:01', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f9eeefd9-34f5-4e45-bd06-2ba1ef45dde5'	System	16 Aug 2020 17:34:20
User entered 'None (1)'	System	16 Aug 2020 17:34:20

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:05', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f9eeefd9-34f5-4e45-bd06-2ba1ef45dde5'	System	16 Aug 2020 17:34:20
User entered 'No (N)'	System	16 Aug 2020 17:34:20

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:09', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f9eeefd9-34f5-4e45-bd06-2ba1ef45dde5'	System	16 Aug 2020 17:34:20
User entered 'No (N)'	System	16 Aug 2020 17:34:20



US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:13', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f9eeefd9-34f5-4e45-bd06-2ba1ef45dde5'	System	16 Aug 2020 17:34:20
User entered 'None (1)'	System	16 Aug 2020 17:34:20

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:19', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f9eeefd9-34f5-4e45-bd06-2ba1ef45dde5'	System	16 Aug 2020 17:34:20
User entered '16 Aug 2020 13:34'	System	16 Aug 2020 17:34:20

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:00:56', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e7509584-c576-4e3d-a9b8-004851de84f4'	System	10 Aug 2020 21:01:45
User entered 'None (0)'	System	10 Aug 2020 21:01:45

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:01:00', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e7509584-c576-4e3d-a9b8-004851de84f4'	System	10 Aug 2020 21:01:45
User entered 'None (0)'	System	10 Aug 2020 21:01:45

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:01:06', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e7509584-c576-4e3d-a9b8-004851de84f4'	System	10 Aug 2020 21:01:45
User entered 'None (0)'	System	10 Aug 2020 21:01:45



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:01:13', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e7509584-c576-4e3d-a9b8-004851de84f4'	System	10 Aug 2020 21:01:45
User entered 'None (0)'	System	10 Aug 2020 21:01:45

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:01:18', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e7509584-c576-4e3d-a9b8-004851de84f4'	System	10 Aug 2020 21:01:45
User entered 'None (0)'	System	10 Aug 2020 21:01:45

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:01:22', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e7509584-c576-4e3d-a9b8-004851de84f4'	System	10 Aug 2020 21:01:45
User entered 'None (0)'	System	10 Aug 2020 21:01:45

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:01:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e7509584-c576-4e3d-a9b8-004851de84f4'	System	10 Aug 2020 21:01:45
User entered 'No (N)'	System	10 Aug 2020 21:01:45

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T17:01:41', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e7509584-c576-4e3d-a9b8-004851de84f4'	System	10 Aug 2020 21:01:45
User entered '10 Aug 2020 17:01'	System	10 Aug 2020 21:01:45

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Aug 2020 16:37'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Aug 2020 19:07'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:52:04



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:39:01', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'de57fef3-1620-44cf-b440-3c9f2025c094'	System	11 Aug 2020 00:39:48
User entered 'None (0)'	System	11 Aug 2020 00:39:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:39:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'de57fef3-1620-44cf-b440-3c9f2025c094'	System	11 Aug 2020 00:39:48
User entered 'None (0)'	System	11 Aug 2020 00:39:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:39:15', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'de57fef3-1620-44cf-b440-3c9f2025c094'	System	11 Aug 2020 00:39:48
User entered 'None (0)'	System	11 Aug 2020 00:39:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:39:19', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'de57fef3-1620-44cf-b440-3c9f2025c094'	System	11 Aug 2020 00:39:48
User entered 'None (0)'	System	11 Aug 2020 00:39:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:39:23', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'de57fef3-1620-44cf-b440-3c9f2025c094'	System	11 Aug 2020 00:39:48
User entered 'None (0)'	System	11 Aug 2020 00:39:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:39:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'de57fef3-1620-44cf-b440-3c9f2025c094'	System	11 Aug 2020 00:39:48
User entered 'None (0)'	System	11 Aug 2020 00:39:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:39:41', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'de57fef3-1620-44cf-b440-3c9f2025c094'	System	11 Aug 2020 00:39:48
User entered 'No (N)'	System	11 Aug 2020 00:39:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-10T20:39:45', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'de57fef3-1620-44cf-b440-3c9f2025c094'	System	11 Aug 2020 00:39:48
User entered '10 Aug 2020 20:39'	System	11 Aug 2020 00:39:48



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Aug 2020 20:02'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 2'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:26:07', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '94d79eb7-4cb6-45bd-811d-86a1da8885ca'	System	11 Aug 2020 17:26:49
User entered 'None (0)'	System	11 Aug 2020 17:26:49

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:26:04', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '94d79eb7-4cb6-45bd-811d-86a1da8885ca'	System	11 Aug 2020 17:26:49
User entered 'None (0)'	System	11 Aug 2020 17:26:49

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:26:14', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '94d79eb7-4cb6-45bd-811d-86a1da8885ca'	System	11 Aug 2020 17:26:49
User entered 'None (0)'	System	11 Aug 2020 17:26:49

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:26:19', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '94d79eb7-4cb6-45bd-811d-86a1da8885ca'	System	11 Aug 2020 17:26:49
User entered 'None (0)'	System	11 Aug 2020 17:26:49

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:26:28', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '94d79eb7-4cb6-45bd-811d-86a1da8885ca'	System	11 Aug 2020 17:26:49
User entered 'None (0)'	System	11 Aug 2020 17:26:49



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:26:31', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '94d79eb7-4cb6-45bd-811d-86a1da8885ca'	System	11 Aug 2020 17:26:49
User entered 'None (0)'	System	11 Aug 2020 17:26:49

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:26:38', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '94d79eb7-4cb6-45bd-811d-86a1da8885ca'	System	11 Aug 2020 17:26:49
User entered 'No (N)'	System	11 Aug 2020 17:26:49

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-11T13:26:46', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '94d79eb7-4cb6-45bd-811d-86a1da8885ca'	System	11 Aug 2020 17:26:49
User entered '11 Aug 2020 13:26'	System	11 Aug 2020 17:26:49

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 3'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:22:01', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '328bfb9e-8ce3-450a-9db7-d52f91afb936'	System	13 Aug 2020 00:22:38
User entered 'None (0)'	System	13 Aug 2020 00:22:38

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:22:05', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '328bfb9e-8ce3-450a-9db7-d52f91afb936'	System	13 Aug 2020 00:22:38
User entered 'None (0)'	System	13 Aug 2020 00:22:38



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:22:09', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '328bfb9e-8ce3-450a-9db7-d52f91afb936'	System	13 Aug 2020 00:22:38
User entered 'None (0)'	System	13 Aug 2020 00:22:38

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:22:14', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '328bfb9e-8ce3-450a-9db7-d52f91afb936'	System	13 Aug 2020 00:22:38
User entered 'None (0)'	System	13 Aug 2020 00:22:38

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:22:18', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '328bfb9e-8ce3-450a-9db7-d52f91afb936'	System	13 Aug 2020 00:22:38
User entered 'None (0)'	System	13 Aug 2020 00:22:38

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:22:21', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '328bfb9e-8ce3-450a-9db7-d52f91afb936'	System	13 Aug 2020 00:22:38
User entered 'None (0)'	System	13 Aug 2020 00:22:38

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:22:29', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '328bfb9e-8ce3-450a-9db7-d52f91afb936'	System	13 Aug 2020 00:22:38
User entered 'No (N)'	System	13 Aug 2020 00:22:38

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-12T20:22:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '328bfb9e-8ce3-450a-9db7-d52f91afb936'	System	13 Aug 2020 00:22:38
User entered '12 Aug 2020 20:22'	System	13 Aug 2020 00:22:38

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:52:04



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 4'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:31', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f1afb690-50d0-4854-9dc9-6f35da105075'	System	14 Aug 2020 02:25:06
User entered 'None (0)'	System	14 Aug 2020 02:25:06

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:34', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f1afb690-50d0-4854-9dc9-6f35da105075'	System	14 Aug 2020 02:25:06
User entered 'None (0)'	System	14 Aug 2020 02:25:06

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:41', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f1afb690-50d0-4854-9dc9-6f35da105075'	System	14 Aug 2020 02:25:06
User entered 'None (0)'	System	14 Aug 2020 02:25:06

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:44', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f1afb690-50d0-4854-9dc9-6f35da105075'	System	14 Aug 2020 02:25:06
User entered 'None (0)'	System	14 Aug 2020 02:25:06

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:47', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f1afb690-50d0-4854-9dc9-6f35da105075'	System	14 Aug 2020 02:25:06
User entered 'None (0)'	System	14 Aug 2020 02:25:06

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:50', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f1afb690-50d0-4854-9dc9-6f35da105075'	System	14 Aug 2020 02:25:06
User entered 'None (0)'	System	14 Aug 2020 02:25:06

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:24:58', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f1afb690-50d0-4854-9dc9-6f35da105075'	System	14 Aug 2020 02:25:06
User entered 'No (N)'	System	14 Aug 2020 02:25:06



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-13T22:25:03', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f1afb690-50d0-4854-9dc9-6f35da105075'	System	14 Aug 2020 02:25:06
User entered '13 Aug 2020 22:25'	System	14 Aug 2020 02:25:06

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 5'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:27', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7c6c6400-b1ab-4cb1-84a8-c0c7b15a0b62'	System	15 Aug 2020 01:29:05
User entered 'None (0)'	System	15 Aug 2020 01:29:05

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:31', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7c6c6400-b1ab-4cb1-84a8-c0c7b15a0b62'	System	15 Aug 2020 01:29:05
User entered 'None (0)'	System	15 Aug 2020 01:29:05

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7c6c6400-b1ab-4cb1-84a8-c0c7b15a0b62'	System	15 Aug 2020 01:29:05
User entered 'None (0)'	System	15 Aug 2020 01:29:05

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:39', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7c6c6400-b1ab-4cb1-84a8-c0c7b15a0b62'	System	15 Aug 2020 01:29:05
User entered 'None (0)'	System	15 Aug 2020 01:29:05



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:42', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7c6c6400-b1ab-4cb1-84a8-c0c7b15a0b62'	System	15 Aug 2020 01:29:05
User entered 'None (0)'	System	15 Aug 2020 01:29:05

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:45', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7c6c6400-b1ab-4cb1-84a8-c0c7b15a0b62'	System	15 Aug 2020 01:29:05
User entered 'None (0)'	System	15 Aug 2020 01:29:05

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:28:54', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7c6c6400-b1ab-4cb1-84a8-c0c7b15a0b62'	System	15 Aug 2020 01:29:05
User entered 'No (N)'	System	15 Aug 2020 01:29:05

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-14T21:29:02', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7c6c6400-b1ab-4cb1-84a8-c0c7b15a0b62'	System	15 Aug 2020 01:29:05
User entered '14 Aug 2020 21:29'	System	15 Aug 2020 01:29:05

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 6'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:38:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '758e65f1-674e-4c1f-8155-08a4f27ec908'	System	16 Aug 2020 01:38:48
User entered 'None (0)'	System	16 Aug 2020 01:38:48



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:38:13', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '758e65f1-674e-4c1f-8155-08a4f27ec908'	System	16 Aug 2020 01:38:48
User entered 'None (0)'	System	16 Aug 2020 01:38:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:38:17', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '758e65f1-674e-4c1f-8155-08a4f27ec908'	System	16 Aug 2020 01:38:48
User entered 'None (0)'	System	16 Aug 2020 01:38:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:38:25', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '758e65f1-674e-4c1f-8155-08a4f27ec908'	System	16 Aug 2020 01:38:48
User entered 'None (0)'	System	16 Aug 2020 01:38:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:38:28', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '758e65f1-674e-4c1f-8155-08a4f27ec908'	System	16 Aug 2020 01:38:48
User entered 'None (0)'	System	16 Aug 2020 01:38:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:38:33', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '758e65f1-674e-4c1f-8155-08a4f27ec908'	System	16 Aug 2020 01:38:48
User entered 'None (0)'	System	16 Aug 2020 01:38:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:38:39', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '758e65f1-674e-4c1f-8155-08a4f27ec908'	System	16 Aug 2020 01:38:48
User entered 'No (N)'	System	16 Aug 2020 01:38:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-15T21:38:46', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '758e65f1-674e-4c1f-8155-08a4f27ec908'	System	16 Aug 2020 01:38:48
User entered '15 Aug 2020 21:38'	System	16 Aug 2020 01:38:48

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:52:04



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 7'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:25', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6892d836-1e6a-4917-aaf9-55d42f5c3944'	System	16 Aug 2020 17:35:04
User entered 'None (0)'	System	16 Aug 2020 17:35:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:28', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6892d836-1e6a-4917-aaf9-55d42f5c3944'	System	16 Aug 2020 17:35:04
User entered 'None (0)'	System	16 Aug 2020 17:35:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:33', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6892d836-1e6a-4917-aaf9-55d42f5c3944'	System	16 Aug 2020 17:35:04
User entered 'None (0)'	System	16 Aug 2020 17:35:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:38', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6892d836-1e6a-4917-aaf9-55d42f5c3944'	System	16 Aug 2020 17:35:04
User entered 'None (0)'	System	16 Aug 2020 17:35:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:42', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6892d836-1e6a-4917-aaf9-55d42f5c3944'	System	16 Aug 2020 17:35:04
User entered 'None (0)'	System	16 Aug 2020 17:35:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:45', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6892d836-1e6a-4917-aaf9-55d42f5c3944'	System	16 Aug 2020 17:35:04
User entered 'None (0)'	System	16 Aug 2020 17:35:04



US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:34:50', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6892d836-1e6a-4917-aaf9-55d42f5c3944'	System	16 Aug 2020 17:35:04
User entered 'No (N)'	System	16 Aug 2020 17:35:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-08-16T13:35:03', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6892d836-1e6a-4917-aaf9-55d42f5c3944'	System	16 Aug 2020 17:35:04
User entered '16 Aug 2020 13:35'	System	16 Aug 2020 17:35:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:52:04

US3482005

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 20:04:25

US3482005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 20:04:25

US3482005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 20:04:25

US3482005

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 20:04:25



US3482005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 20:04:30

US3482005

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'I'	System	18 Aug 2020 20:04:30

US3482005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:50:45

US3482005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:50:45

US3482005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:50:45

US3482005

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:50:45

US3482005

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:50:50

**US3482005**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:44:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:59:30
User entered 'I'	System	26 Aug 2020 20:50:50



US3482005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:53
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:01:23

US3482005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:53
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:01:23

US3482005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:53
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:01:23

US3482005

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:53
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:01:23

US3482005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:53
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:01:28

US3482005

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:03:53
User entered 'I'	System	31 Aug 2020 16:01:28

US3482005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Yes (Y)'	Mary Bower (b) (4)	09 Sep 2020 14:56:29

US3482005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:41:45
User entered '9 Sep 2020'	Mary Bower (b) (4) (b) (4)	09 Sep 2020 14:56:29



US3482005

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[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 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Clinic (Clinic)'	Mary Bower (b) (4)	09 Sep 2020 14:56:29

**US3482005**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:44:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'VISIT2'	System	09 Sep 2020 14:56:29

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User accepted default value 'Pre-Dose (PREDOSE)'	Mary Bower (b) (4) (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Yes (Y)'	Mary Bower (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '9 Sep 2020'	Mary Bower (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '10:12'	Mary Bower (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered '9 Sep 2020 10:12'	System	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '98.3' F	Mary Bower (b) (4)	09 Sep 2020 16:04:45



US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Oral (Oral)'	Mary Bower (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	Mary Bower (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '71'	Mary Bower (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'bpm'	System	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '16'	Mary Bower (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'breaths/min'	System	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '137'	Mary Bower (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'mmHg'	System	09 Sep 2020 16:04:45



US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '85'	Mary Bower (b) (4)	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'mmHg'	System	09 Sep 2020 16:04:45

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User accepted default value 'Post-Dose (POSTDOSE)'	Mary Bower (b) (4) (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Yes (Y)'	Mary Bower (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '9 Sep 2020'	Mary Bower (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '11:31'	Mary Bower (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered '9 Sep 2020 11:31'	System	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '97.9' F	Mary Bower (b) (4)	09 Sep 2020 16:06:11



US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Oral (Oral)'	Mary Bower (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	Mary Bower (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '90'	Mary Bower (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'bpm'	System	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '16'	Mary Bower (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'breaths/min'	System	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '134'	Mary Bower (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'mmHg'	System	09 Sep 2020 16:06:11



US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '81'	Mary Bower (b) (4)	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'mmHg'	System	09 Sep 2020 16:06:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Yes (Y)'	Mary Bower (b) (4)	09 Sep 2020 15:09:59

US3482005

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '9 Sep 2020'	Mary Bower (b) (4)	09 Sep 2020 15:09:59

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:38:22
User entered 'Yes (Y)'	Mary Bower (b) (4) (b) (4)	09 Sep 2020 15:10:43

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:38:22
User entered empty.	Mary Bower (b) (4) (b) (4)	09 Sep 2020 15:10:43

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:38:22
User entered empty.	Mary Bower (b) (4) (b) (4)	09 Sep 2020 15:10:43

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 15:10:43



US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:38:22
User entered '9 Sep 2020'	Mary Bower (b) (4) (b) (4)	09 Sep 2020 15:10:43

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:38:22
User entered '11:01'	Mary Bower (b) (4) (b) (4)	09 Sep 2020 15:10:43

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered '9 Sep 2020 11:01'	System	09 Sep 2020 15:10:43

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:38:22
User entered 'Left Arm (LEFT ARM)'	Mary Bower (b) (4) (b) (4)	09 Sep 2020 15:10:43

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:38:22
User entered 'ONCE'	System	09 Sep 2020 15:10:43

US3482005

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 15:10:43

US3482005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	Mary Bower (b) (4)	09 Sep 2020 15:11:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '9 Sep 2020'	Mary Bower (b) (4)	09 Sep 2020 15:11:11



US3482005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10:38'	Mary Bower (b) (4)	09 Sep 2020 15:11:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered '9 Sep 2020 10:38'	System	09 Sep 2020 15:11:11

US3482005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:44:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	09 Sep 2020 15:12:00
System	System	09 Sep 2020 15:12:00
User entered '9 Sep 2020' reason for change: Data Entry Error	Mary Bower (b) (4)	09 Sep 2020 15:12:00
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered empty.	System	09 Sep 2020 15:11:50
	Mary Bower (b) (4)	09 Sep 2020 15:11:50
	(b) (4)	

US3482005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mary Bower (b) (4) (b) (4)	09 Sep 2020 15:11:50

US3482005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	Mary Bower (b) (4)	09 Sep 2020 15:11:50

US3482005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '10:42'	Mary Bower (b) (4)	09 Sep 2020 15:11:50

US3482005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:44:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered '9 Sep 2020 10:42'	System	09 Sep 2020 15:12:00
User entered empty.	System	09 Sep 2020 15:11:50

US3482005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mary Bower (b) (4) (b) (4)	09 Sep 2020 15:11:50



US3482005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'No (N)'	Mary Bower (b) (4)	09 Sep 2020 15:11:50

US3482005

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	Mary Bower (b) (4)	09 Sep 2020 15:11:50

**US3482005**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered empty.	System	09 Sep 2020 15:11:50

US3482005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	Mary Bower (b) (4)	09 Sep 2020 16:06:18

US3482005

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'I'	System	09 Sep 2020 16:06:18

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:38:23', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1fe2e1ff-ae32-4c8a-b3ca-6810198d4e2a'	System	09 Sep 2020 15:38:51
User entered 'Yes (Y)'	System	09 Sep 2020 15:38:51

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:38:31', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1fe2e1ff-ae32-4c8a-b3ca-6810198d4e2a'	System	09 Sep 2020 15:38:51
User entered '97.9'	System	09 Sep 2020 15:38:51



US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:38:37', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1fe2e1ff-ae32-4c8a-b3ca-6810198d4e2a'	System	09 Sep 2020 15:38:51
User entered 'No (N)'	System	09 Sep 2020 15:38:51

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:38:45', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1fe2e1ff-ae32-4c8a-b3ca-6810198d4e2a'	System	09 Sep 2020 15:38:51
User entered '09 Sep 2020 11:38'	System	09 Sep 2020 15:38:51

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '09 Sep 2020 11:21'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '09 Sep 2020 13:51'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:54:25', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e81cceb8-038b-468d-a738-0a7077fbac05'	System	10 Sep 2020 01:54:42
User entered 'Yes (Y)'	System	10 Sep 2020 01:54:42

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:54:32', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e81cceb8-038b-468d-a738-0a7077fbac05'	System	10 Sep 2020 01:54:42
User entered '97.6'	System	10 Sep 2020 01:54:42

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:54:37', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e81cceb8-038b-468d-a738-0a7077fbac05'	System	10 Sep 2020 01:54:42
User entered 'No (N)'	System	10 Sep 2020 01:54:42



US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:54:41', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e81cceb8-038b-468d-a738-0a7077fbac05'	System	10 Sep 2020 01:54:42
User entered '09 Sep 2020 21:54'	System	10 Sep 2020 01:54:42

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '09 Sep 2020 14:46'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 2'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:25:52', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '04584aca-48d4-47af-89ee-3a8d1179ab53'	System	11 Sep 2020 01:26:17
User entered 'Yes (Y)'	System	11 Sep 2020 01:26:17

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:26:03', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '04584aca-48d4-47af-89ee-3a8d1179ab53'	System	11 Sep 2020 01:26:17
User entered '96.8'	System	11 Sep 2020 01:26:17

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:26:08', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '04584aca-48d4-47af-89ee-3a8d1179ab53'	System	11 Sep 2020 01:26:17
User entered 'No (N)'	System	11 Sep 2020 01:26:17

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:26:14', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '04584aca-48d4-47af-89ee-3a8d1179ab53'	System	11 Sep 2020 01:26:17
User entered '10 Sep 2020 21:26'	System	11 Sep 2020 01:26:17



US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 3'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:04:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6225cd67-94fb-4cf9-a88f-35d35cda19ba'	System	11 Sep 2020 16:07:38
User entered 'Yes (Y)'	System	11 Sep 2020 16:07:38

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:05:05', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6225cd67-94fb-4cf9-a88f-35d35cda19ba'	System	11 Sep 2020 16:07:38
User entered '97.6'	System	11 Sep 2020 16:07:38

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:05:09', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6225cd67-94fb-4cf9-a88f-35d35cda19ba'	System	11 Sep 2020 16:07:38
User entered 'No (N)'	System	11 Sep 2020 16:07:38

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:05:13', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '6225cd67-94fb-4cf9-a88f-35d35cda19ba'	System	11 Sep 2020 16:07:38
User entered '11 Sep 2020 12:05'	System	11 Sep 2020 16:07:38

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 15:10:43



US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 4'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:34:00', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f28ffa02-dedb-4fa2-9f50-d96e4ae77f8a'	System	13 Sep 2020 02:34:18
User entered 'Yes (Y)'	System	13 Sep 2020 02:34:18

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:34:06', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f28ffa02-dedb-4fa2-9f50-d96e4ae77f8a'	System	13 Sep 2020 02:34:18
User entered '97.2'	System	13 Sep 2020 02:34:18

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:34:11', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f28ffa02-dedb-4fa2-9f50-d96e4ae77f8a'	System	13 Sep 2020 02:34:18
User entered 'No (N)'	System	13 Sep 2020 02:34:18

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:34:16', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f28ffa02-dedb-4fa2-9f50-d96e4ae77f8a'	System	13 Sep 2020 02:34:18
User entered '12 Sep 2020 22:34'	System	13 Sep 2020 02:34:18

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 15:10:43



US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 5'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:41:53', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15da3c04-2437-4db3-b4e0-733133992624'	System	13 Sep 2020 20:42:31
User entered 'Yes (Y)'	System	13 Sep 2020 20:42:31

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:42:20', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15da3c04-2437-4db3-b4e0-733133992624'	System	13 Sep 2020 20:42:31
User entered '98.3'	System	13 Sep 2020 20:42:31

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:42:24', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15da3c04-2437-4db3-b4e0-733133992624'	System	13 Sep 2020 20:42:31
User entered 'No (N)'	System	13 Sep 2020 20:42:31

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:42:29', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15da3c04-2437-4db3-b4e0-733133992624'	System	13 Sep 2020 20:42:31
User entered '13 Sep 2020 16:42'	System	13 Sep 2020 20:42:31

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 6'	System	09 Sep 2020 15:10:43



US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:09:32', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'b4ea168c-a1b3-469d-bdb9-46c2f615cc5c'	System	14 Sep 2020 16:12:08
User entered 'Yes (Y)'	System	14 Sep 2020 16:12:08

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:09:39', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'b4ea168c-a1b3-469d-bdb9-46c2f615cc5c'	System	14 Sep 2020 16:12:08
User entered '97.7'	System	14 Sep 2020 16:12:08

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:09:43', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'b4ea168c-a1b3-469d-bdb9-46c2f615cc5c'	System	14 Sep 2020 16:12:08
User entered 'No (N)'	System	14 Sep 2020 16:12:08

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:09:48', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'b4ea168c-a1b3-469d-bdb9-46c2f615cc5c'	System	14 Sep 2020 16:12:08
User entered '14 Sep 2020 12:09'	System	14 Sep 2020 16:12:08

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 7'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:54:59', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fc54559f-4743-4657-ada3-afbcbe652b01'	System	16 Sep 2020 01:55:18
User entered 'Yes (Y)'	System	16 Sep 2020 01:55:18



US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:07', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fc54559f-4743-4657-ada3-afbcbe652b01'	System	16 Sep 2020 01:55:18
User entered '97.3'	System	16 Sep 2020 01:55:18

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:11', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fc54559f-4743-4657-ada3-afbcbe652b01'	System	16 Sep 2020 01:55:18
User entered 'No (N)'	System	16 Sep 2020 01:55:18

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:16', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'fc54559f-4743-4657-ada3-afbcbe652b01'	System	16 Sep 2020 01:55:18
User entered '15 Sep 2020 21:55'	System	16 Sep 2020 01:55:18

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:38:53', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2423319e-3a1f-45a6-b6ec-db8226595c3c'	System	09 Sep 2020 15:39:18
User entered 'None (1)'	System	09 Sep 2020 15:39:18

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:38:57', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2423319e-3a1f-45a6-b6ec-db8226595c3c'	System	09 Sep 2020 15:39:18
User entered 'No (N)'	System	09 Sep 2020 15:39:18



US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:01', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2423319e-3a1f-45a6-b6ec-db8226595c3c'	System	09 Sep 2020 15:39:18
User entered 'No (N)'	System	09 Sep 2020 15:39:18

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:07', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2423319e-3a1f-45a6-b6ec-db8226595c3c'	System	09 Sep 2020 15:39:18
User entered 'None (1)'	System	09 Sep 2020 15:39:18

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:12', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2423319e-3a1f-45a6-b6ec-db8226595c3c'	System	09 Sep 2020 15:39:18
User entered '09 Sep 2020 11:39'	System	09 Sep 2020 15:39:18

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '09 Sep 2020 11:21'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '09 Sep 2020 13:51'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:09', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a12d71d6-7948-43ac-a09c-deae4ef9cdc4'	System	10 Sep 2020 01:53:37
User entered 'None (1)'	System	10 Sep 2020 01:53:37

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:14', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a12d71d6-7948-43ac-a09c-deae4ef9cdc4'	System	10 Sep 2020 01:53:37
User entered 'No (N)'	System	10 Sep 2020 01:53:37



US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:22', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a12d71d6-7948-43ac-a09c-deae4ef9cdc4'	System	10 Sep 2020 01:53:37
User entered 'No (N)'	System	10 Sep 2020 01:53:37

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:30', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a12d71d6-7948-43ac-a09c-deae4ef9cdc4'	System	10 Sep 2020 01:53:37
User entered 'None (1)'	System	10 Sep 2020 01:53:37

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a12d71d6-7948-43ac-a09c-deae4ef9cdc4'	System	10 Sep 2020 01:53:37
User entered '09 Sep 2020 21:53'	System	10 Sep 2020 01:53:37

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '09 Sep 2020 14:46'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 2'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:26:28', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '5cb9c6aa-cbc5-4dc4-a10c-8c5fafb18c3a'	System	11 Sep 2020 01:27:10
User entered 'None (1)'	System	11 Sep 2020 01:27:10

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:26:32', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '5cb9c6aa-cbc5-4dc4-a10c-8c5fafb18c3a'	System	11 Sep 2020 01:27:10
User entered 'No (N)'	System	11 Sep 2020 01:27:10



US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:26:36', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '5cb9c6aa-cbc5-4dc4-a10c-8c5fafb18c3a'	System	11 Sep 2020 01:27:10
User entered 'No (N)'	System	11 Sep 2020 01:27:10

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:26:54', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '5cb9c6aa-cbc5-4dc4-a10c-8c5fafb18c3a'	System	11 Sep 2020 01:27:10
User entered 'None (1)'	System	11 Sep 2020 01:27:10

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:26:59', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '5cb9c6aa-cbc5-4dc4-a10c-8c5fafb18c3a'	System	11 Sep 2020 01:27:10
User entered '10 Sep 2020 21:26'	System	11 Sep 2020 01:27:10

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 3'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:05:18', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '21bfe06a-6d14-4bc9-bf32-87dddbaf7a84'	System	11 Sep 2020 16:07:58
User entered 'None (1)'	System	11 Sep 2020 16:07:58

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:05:23', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '21bfe06a-6d14-4bc9-bf32-87dddbaf7a84'	System	11 Sep 2020 16:07:58
User entered 'No (N)'	System	11 Sep 2020 16:07:58



US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:05:27', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '21bfe06a-6d14-4bc9-bf32-87dddbaf7a84'	System	11 Sep 2020 16:07:58
User entered 'No (N)'	System	11 Sep 2020 16:07:58

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:05:31', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '21bfe06a-6d14-4bc9-bf32-87dddbaf7a84'	System	11 Sep 2020 16:07:58
User entered 'None (1)'	System	11 Sep 2020 16:07:58

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:05:57', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '21bfe06a-6d14-4bc9-bf32-87dddbaf7a84'	System	11 Sep 2020 16:07:58
User entered '11 Sep 2020 12:05'	System	11 Sep 2020 16:07:58

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 4'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:32:37', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e22f8de1-2a31-40ac-88e8-edd5803b25fa'	System	13 Sep 2020 02:33:06
User entered 'None (1)'	System	13 Sep 2020 02:33:06

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:32:42', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e22f8de1-2a31-40ac-88e8-edd5803b25fa'	System	13 Sep 2020 02:33:06
User entered 'No (N)'	System	13 Sep 2020 02:33:06



US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:32:50', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e22f8de1-2a31-40ac-88e8-edd5803b25fa'	System	13 Sep 2020 02:33:06
User entered 'No (N)'	System	13 Sep 2020 02:33:06

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:32:55', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e22f8de1-2a31-40ac-88e8-edd5803b25fa'	System	13 Sep 2020 02:33:06
User entered 'None (1)'	System	13 Sep 2020 02:33:06

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:33:02', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e22f8de1-2a31-40ac-88e8-edd5803b25fa'	System	13 Sep 2020 02:33:06
User entered '12 Sep 2020 22:33'	System	13 Sep 2020 02:33:06

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 5'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:42:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7e1be59f-ef58-46e9-bd89-0b1c2d5d0ed6'	System	13 Sep 2020 20:42:56
User entered 'None (1)'	System	13 Sep 2020 20:42:56

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:42:40', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7e1be59f-ef58-46e9-bd89-0b1c2d5d0ed6'	System	13 Sep 2020 20:42:56
User entered 'No (N)'	System	13 Sep 2020 20:42:56



US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:42:44', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7e1be59f-ef58-46e9-bd89-0b1c2d5d0ed6'	System	13 Sep 2020 20:42:56
User entered 'No (N)'	System	13 Sep 2020 20:42:56

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:42:50', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7e1be59f-ef58-46e9-bd89-0b1c2d5d0ed6'	System	13 Sep 2020 20:42:56
User entered 'None (1)'	System	13 Sep 2020 20:42:56

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:42:54', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '7e1be59f-ef58-46e9-bd89-0b1c2d5d0ed6'	System	13 Sep 2020 20:42:56
User entered '13 Sep 2020 16:42'	System	13 Sep 2020 20:42:56

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 6'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:09:57', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e0bdce31-8303-48ee-8396-e93a3360c9a0'	System	14 Sep 2020 16:12:23
User entered 'None (1)'	System	14 Sep 2020 16:12:23

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:01', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e0bdce31-8303-48ee-8396-e93a3360c9a0'	System	14 Sep 2020 16:12:23
User entered 'No (N)'	System	14 Sep 2020 16:12:23



US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:09', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e0bdce31-8303-48ee-8396-e93a3360c9a0'	System	14 Sep 2020 16:12:23
User entered 'No (N)'	System	14 Sep 2020 16:12:23

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:16', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e0bdce31-8303-48ee-8396-e93a3360c9a0'	System	14 Sep 2020 16:12:23
User entered 'None (1)'	System	14 Sep 2020 16:12:23

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:20', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e0bdce31-8303-48ee-8396-e93a3360c9a0'	System	14 Sep 2020 16:12:23
User entered '14 Sep 2020 12:10'	System	14 Sep 2020 16:12:23

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 7'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:23', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd34a3ebf-c3a0-48d9-aff6-613f99e33a1f'	System	16 Sep 2020 01:55:43
User entered 'None (1)'	System	16 Sep 2020 01:55:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:27', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd34a3ebf-c3a0-48d9-aff6-613f99e33a1f'	System	16 Sep 2020 01:55:43
User entered 'No (N)'	System	16 Sep 2020 01:55:43



US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:30', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd34a3ebf-c3a0-48d9-aff6-613f99e33a1f'	System	16 Sep 2020 01:55:43
User entered 'No (N)'	System	16 Sep 2020 01:55:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:34', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd34a3ebf-c3a0-48d9-aff6-613f99e33a1f'	System	16 Sep 2020 01:55:43
User entered 'None (1)'	System	16 Sep 2020 01:55:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:38', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd34a3ebf-c3a0-48d9-aff6-613f99e33a1f'	System	16 Sep 2020 01:55:43
User entered '15 Sep 2020 21:55'	System	16 Sep 2020 01:55:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:19', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9d31be8e-2cef-45fa-ba40-aa2c98f7d725'	System	09 Sep 2020 15:39:46
User entered 'None (0)'	System	09 Sep 2020 15:39:46

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:22', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9d31be8e-2cef-45fa-ba40-aa2c98f7d725'	System	09 Sep 2020 15:39:46
User entered 'None (0)'	System	09 Sep 2020 15:39:46



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:26', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9d31be8e-2cef-45fa-ba40-aa2c98f7d725'	System	09 Sep 2020 15:39:46
User entered 'None (0)'	System	09 Sep 2020 15:39:46

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:29', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9d31be8e-2cef-45fa-ba40-aa2c98f7d725'	System	09 Sep 2020 15:39:46
User entered 'None (0)'	System	09 Sep 2020 15:39:46

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:32', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9d31be8e-2cef-45fa-ba40-aa2c98f7d725'	System	09 Sep 2020 15:39:46
User entered 'None (0)'	System	09 Sep 2020 15:39:46

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9d31be8e-2cef-45fa-ba40-aa2c98f7d725'	System	09 Sep 2020 15:39:46
User entered 'None (0)'	System	09 Sep 2020 15:39:46

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:41', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9d31be8e-2cef-45fa-ba40-aa2c98f7d725'	System	09 Sep 2020 15:39:46
User entered 'No (N)'	System	09 Sep 2020 15:39:46

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T11:39:44', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9d31be8e-2cef-45fa-ba40-aa2c98f7d725'	System	09 Sep 2020 15:39:46
User entered '09 Sep 2020 11:39'	System	09 Sep 2020 15:39:46

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '09 Sep 2020 11:21'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '09 Sep 2020 13:51'	System	09 Sep 2020 15:10:43



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:42', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ed1901b8-a779-4297-bbc1-85bf2d089e33'	System	10 Sep 2020 01:54:12
User entered 'None (0)'	System	10 Sep 2020 01:54:12

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:45', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ed1901b8-a779-4297-bbc1-85bf2d089e33'	System	10 Sep 2020 01:54:12
User entered 'None (0)'	System	10 Sep 2020 01:54:12

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:49', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ed1901b8-a779-4297-bbc1-85bf2d089e33'	System	10 Sep 2020 01:54:12
User entered 'None (0)'	System	10 Sep 2020 01:54:12

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:51', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ed1901b8-a779-4297-bbc1-85bf2d089e33'	System	10 Sep 2020 01:54:12
User entered 'None (0)'	System	10 Sep 2020 01:54:12

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:54', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ed1901b8-a779-4297-bbc1-85bf2d089e33'	System	10 Sep 2020 01:54:12
User entered 'None (0)'	System	10 Sep 2020 01:54:12

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:53:58', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ed1901b8-a779-4297-bbc1-85bf2d089e33'	System	10 Sep 2020 01:54:12
User entered 'None (0)'	System	10 Sep 2020 01:54:12

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:54:03', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ed1901b8-a779-4297-bbc1-85bf2d089e33'	System	10 Sep 2020 01:54:12
User entered 'No (N)'	System	10 Sep 2020 01:54:12



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-09T21:54:07', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ed1901b8-a779-4297-bbc1-85bf2d089e33'	System	10 Sep 2020 01:54:12
User entered '09 Sep 2020 21:54'	System	10 Sep 2020 01:54:12

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '09 Sep 2020 14:46'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 2'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:27:05', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ac346a52-5b7c-4927-b2d3-7fc8f12dd323'	System	11 Sep 2020 01:27:36
User entered 'None (0)'	System	11 Sep 2020 01:27:36

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:27:08', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ac346a52-5b7c-4927-b2d3-7fc8f12dd323'	System	11 Sep 2020 01:27:36
User entered 'None (0)'	System	11 Sep 2020 01:27:36

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:27:11', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ac346a52-5b7c-4927-b2d3-7fc8f12dd323'	System	11 Sep 2020 01:27:36
User entered 'None (0)'	System	11 Sep 2020 01:27:36

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:27:15', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ac346a52-5b7c-4927-b2d3-7fc8f12dd323'	System	11 Sep 2020 01:27:36
User entered 'None (0)'	System	11 Sep 2020 01:27:36



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:27:19', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ac346a52-5b7c-4927-b2d3-7fc8f12dd323'	System	11 Sep 2020 01:27:36
User entered 'None (0)'	System	11 Sep 2020 01:27:36

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:27:21', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ac346a52-5b7c-4927-b2d3-7fc8f12dd323'	System	11 Sep 2020 01:27:36
User entered 'None (0)'	System	11 Sep 2020 01:27:36

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:27:27', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ac346a52-5b7c-4927-b2d3-7fc8f12dd323'	System	11 Sep 2020 01:27:36
User entered 'No (N)'	System	11 Sep 2020 01:27:36

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-10T21:27:30', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'ac346a52-5b7c-4927-b2d3-7fc8f12dd323'	System	11 Sep 2020 01:27:36
User entered '10 Sep 2020 21:27'	System	11 Sep 2020 01:27:36

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 3'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:06:03', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'da8fe4bb-a4d2-4f18-9056-ff4ecbf91dc9'	System	11 Sep 2020 16:08:18
User entered 'None (0)'	System	11 Sep 2020 16:08:18



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:06:07', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'da8fe4bb-a4d2-4f18-9056-ff4ecbf91dc9'	System	11 Sep 2020 16:08:18
User entered 'None (0)'	System	11 Sep 2020 16:08:18

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:06:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'da8fe4bb-a4d2-4f18-9056-ff4ecbf91dc9'	System	11 Sep 2020 16:08:18
User entered 'None (0)'	System	11 Sep 2020 16:08:18

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:06:14', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'da8fe4bb-a4d2-4f18-9056-ff4ecbf91dc9'	System	11 Sep 2020 16:08:18
User entered 'None (0)'	System	11 Sep 2020 16:08:18

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:06:17', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'da8fe4bb-a4d2-4f18-9056-ff4ecbf91dc9'	System	11 Sep 2020 16:08:18
User entered 'None (0)'	System	11 Sep 2020 16:08:18

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:06:30', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'da8fe4bb-a4d2-4f18-9056-ff4ecbf91dc9'	System	11 Sep 2020 16:08:18
User entered 'None (0)'	System	11 Sep 2020 16:08:18

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:06:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'da8fe4bb-a4d2-4f18-9056-ff4ecbf91dc9'	System	11 Sep 2020 16:08:18
User entered 'No (N)'	System	11 Sep 2020 16:08:18

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-11T12:06:39', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'da8fe4bb-a4d2-4f18-9056-ff4ecbf91dc9'	System	11 Sep 2020 16:08:18
User entered '11 Sep 2020 12:06'	System	11 Sep 2020 16:08:18

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 15:10:43



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 4'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:33:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'bc569f8f-270a-46c5-99d3-2c1f05ba238f'	System	13 Sep 2020 02:33:55
User entered 'None (0)'	System	13 Sep 2020 02:33:55

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:33:30', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'bc569f8f-270a-46c5-99d3-2c1f05ba238f' User entered 'None (0)'	System	13 Sep 2020 02:33:55
	System	13 Sep 2020 02:33:55

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:33:34', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'bc569f8f-270a-46c5-99d3-2c1f05ba238f'	System	13 Sep 2020 02:33:55
User entered 'None (0)'	System	13 Sep 2020 02:33:55

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:33:37', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'bc569f8f-270a-46c5-99d3-2c1f05ba238f' User entered 'None (0)'	System	13 Sep 2020 02:33:55
	System	13 Sep 2020 02:33:55

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:33:39', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'bc569f8f-270a-46c5-99d3-2c1f05ba238f' User entered 'None (0)'	System	13 Sep 2020 02:33:55
	System	13 Sep 2020 02:33:55

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:33:43', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'bc569f8f-270a-46c5-99d3-2c1f05ba238f' User entered 'None (0)'	System	13 Sep 2020 02:33:55
	System	13 Sep 2020 02:33:55



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:33:47', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'bc569f8f-270a-46c5-99d3-2c1f05ba238f'	System	13 Sep 2020 02:33:55
User entered 'No (N)'	System	13 Sep 2020 02:33:55

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-12T22:33:51', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'bc569f8f-270a-46c5-99d3-2c1f05ba238f' User entered '12 Sep 2020 22:33'	System	13 Sep 2020 02:33:55
	System	13 Sep 2020 02:33:55

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 5'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:42:59', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '32dd5e8f-1a32-4a59-bd6e-0616ddf3a2ef'	System	13 Sep 2020 20:43:29
User entered 'None (0)'	System	13 Sep 2020 20:43:29

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:43:02', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '32dd5e8f-1a32-4a59-bd6e-0616ddf3a2ef'	System	13 Sep 2020 20:43:29
User entered 'None (0)'	System	13 Sep 2020 20:43:29

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:43:07', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '32dd5e8f-1a32-4a59-bd6e-0616ddf3a2ef'	System	13 Sep 2020 20:43:29
User entered 'None (0)'	System	13 Sep 2020 20:43:29



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:43:11', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '32dd5e8f-1a32-4a59-bd6e-0616ddf3a2ef'	System	13 Sep 2020 20:43:29
User entered 'None (0)'	System	13 Sep 2020 20:43:29

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:43:14', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '32dd5e8f-1a32-4a59-bd6e-0616ddf3a2ef'	System	13 Sep 2020 20:43:29
User entered 'None (0)'	System	13 Sep 2020 20:43:29

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:43:18', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '32dd5e8f-1a32-4a59-bd6e-0616ddf3a2ef'	System	13 Sep 2020 20:43:29
User entered 'None (0)'	System	13 Sep 2020 20:43:29

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:43:23', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '32dd5e8f-1a32-4a59-bd6e-0616ddf3a2ef'	System	13 Sep 2020 20:43:29
User entered 'No (N)'	System	13 Sep 2020 20:43:29

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-13T16:43:27', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '32dd5e8f-1a32-4a59-bd6e-0616ddf3a2ef'	System	13 Sep 2020 20:43:29
User entered '13 Sep 2020 16:43'	System	13 Sep 2020 20:43:29

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 6'	System	09 Sep 2020 15:10:43



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:29', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15abb2ba-fcc8-4757-ac3a-971b7e133ad6'	System	14 Sep 2020 16:12:37
User entered 'None (0)'	System	14 Sep 2020 16:12:37

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:31', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15abb2ba-fcc8-4757-ac3a-971b7e133ad6'	System	14 Sep 2020 16:12:37
User entered 'None (0)'	System	14 Sep 2020 16:12:37

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15abb2ba-fcc8-4757-ac3a-971b7e133ad6'	System	14 Sep 2020 16:12:37
User entered 'None (0)'	System	14 Sep 2020 16:12:37

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:50', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15abb2ba-fcc8-4757-ac3a-971b7e133ad6'	System	14 Sep 2020 16:12:37
User entered 'None (0)'	System	14 Sep 2020 16:12:37

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:55', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15abb2ba-fcc8-4757-ac3a-971b7e133ad6'	System	14 Sep 2020 16:12:37
User entered 'None (0)'	System	14 Sep 2020 16:12:37

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:10:57', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15abb2ba-fcc8-4757-ac3a-971b7e133ad6'	System	14 Sep 2020 16:12:37
User entered 'None (0)'	System	14 Sep 2020 16:12:37

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:11:02', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15abb2ba-fcc8-4757-ac3a-971b7e133ad6'	System	14 Sep 2020 16:12:37
User entered 'No (N)'	System	14 Sep 2020 16:12:37

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-14T12:11:05', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '15abb2ba-fcc8-4757-ac3a-971b7e133ad6'	System	14 Sep 2020 16:12:37
User entered '14 Sep 2020 12:11'	System	14 Sep 2020 16:12:37



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	09 Sep 2020 15:10:43
User entered 'Day 7'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:45', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '0c96fd2b-37e5-4f6b-999e-99a97056e0c9'	System	16 Sep 2020 01:56:16
User entered 'None (0)'	System	16 Sep 2020 01:56:16

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:48', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '0c96fd2b-37e5-4f6b-999e-99a97056e0c9'	System	16 Sep 2020 01:56:16
User entered 'None (0)'	System	16 Sep 2020 01:56:16

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:50', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '0c96fd2b-37e5-4f6b-999e-99a97056e0c9'	System	16 Sep 2020 01:56:16
User entered 'None (0)'	System	16 Sep 2020 01:56:16

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:53', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '0c96fd2b-37e5-4f6b-999e-99a97056e0c9'	System	16 Sep 2020 01:56:16
User entered 'None (0)'	System	16 Sep 2020 01:56:16

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:56', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '0c96fd2b-37e5-4f6b-999e-99a97056e0c9'	System	16 Sep 2020 01:56:16
User entered 'None (0)'	System	16 Sep 2020 01:56:16



US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:55:58', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '0c96fd2b-37e5-4f6b-999e-99a97056e0c9'	System	16 Sep 2020 01:56:16
User entered 'None (0)'	System	16 Sep 2020 01:56:16

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:56:06', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '0c96fd2b-37e5-4f6b-999e-99a97056e0c9'	System	16 Sep 2020 01:56:16
User entered 'No (N)'	System	16 Sep 2020 01:56:16

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-09-15T21:56:14', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '0c96fd2b-37e5-4f6b-999e-99a97056e0c9'	System	16 Sep 2020 01:56:16
User entered '15 Sep 2020 21:56'	System	16 Sep 2020 01:56:16

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 15:10:43

US3482005

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:44:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 15:10:43

US3482005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:27

US3482005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:27

US3482005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:27



US3482005

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:27

US3482005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:38

US3482005

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'I'	System	16 Sep 2020 18:22:38

US3482005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:38:33

US3482005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:38:33

US3482005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:38:33

US3482005

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:38:33

US3482005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:38:39



US3482005

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'I'	System	24 Sep 2020 15:38:39

US3482005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:05:51

US3482005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:05:51

US3482005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:05:51

US3482005

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:05:51

US3482005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:05:55

US3482005

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'I'	System	01 Oct 2020 14:05:55

US3482005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:40



US3482005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:41:58
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 17:43:40

US3482005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[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 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:40

US3482005

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'VISIT3'	System	07 Oct 2020 17:43:40

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered empty.	System	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45



US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered empty.	System	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered empty.	System	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered empty.	System	07 Oct 2020 17:43:45



US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered empty.	System	07 Oct 2020 17:43:45

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51

US3482005

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51

US3482005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:49

US3482005

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:43:49

US3482005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:44:02

US3482005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:44:02



US3482005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered '13:25'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:44:02

US3482005

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered '7 Oct 2020 13:25'	System	07 Oct 2020 17:44:02

US3482005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:03:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:44:06

US3482005

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'I'	System	07 Oct 2020 17:44:06

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 64'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[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)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-10-14T18:39:38', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f8f6ae8d-c42b-42a2-a614-1a7202af3310'	System	14 Oct 2020 22:40:12
User entered 'No (N)'	System	14 Oct 2020 22:40:12

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

Have you been exposed to someone with 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)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-10-14T18:39:48', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f8f6ae8d-c42b-42a2-a614-1a7202af3310'	System	14 Oct 2020 22:40:12
User entered 'No (N)'	System	14 Oct 2020 22:40:12

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-10-14T18:40:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f8f6ae8d-c42b-42a2-a614-1a7202af3310'	System	14 Oct 2020 22:40:12
User entered '14 Oct 2020 18:40:10'	System	14 Oct 2020 22:40:12



US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 71'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-10-17T02:48:33', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'c49fb321-6488-4fb8-b876-c68c68d10227'	System	17 Oct 2020 06:48:49
User entered 'No (N)'	System	17 Oct 2020 06:48:49

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

Have you been exposed to someone with 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)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-10-17T02:48:40', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'c49fb321-6488-4fb8-b876-c68c68d10227'	System	17 Oct 2020 06:48:49
User entered 'No (N)'	System	17 Oct 2020 06:48:49

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-10-17T02:48:46', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'c49fb321-6488-4fb8-b876-c68c68d10227'	System	17 Oct 2020 06:48:49
User entered '17 Oct 2020 02:48:46'	System	17 Oct 2020 06:48:49

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 20:52:04



US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 78'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

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)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-10-24T07:07:16', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9a71dc7d-f25f-46f6-a2dd-ccf4349d1023'	System	24 Oct 2020 11:07:33
User entered 'No (N)'	System	24 Oct 2020 11:07:33

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

Have you been exposed to someone with 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)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-10-24T07:07:24', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9a71dc7d-f25f-46f6-a2dd-ccf4349d1023'	System	24 Oct 2020 11:07:33
User entered 'No (N)'	System	24 Oct 2020 11:07:33

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-10-24T07:07:29', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '9a71dc7d-f25f-46f6-a2dd-ccf4349d1023'	System	24 Oct 2020 11:07:33
User entered '24 Oct 2020 07:07:29'	System	24 Oct 2020 11:07:33

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 92'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[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)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02



US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

Have you been exposed to someone with 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)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02



US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02



US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 20:52:04

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:59:02
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered 'Day 99'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[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)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-11-17T22:02:11', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e8eccacb-720e-4a4f-9412-f133ee1e6fd7'	System	18 Nov 2020 03:02:24
User entered 'No (N)'	System	18 Nov 2020 03:02:24

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

Have you been exposed to someone with 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)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-11-17T22:02:16', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e8eccacb-720e-4a4f-9412-f133ee1e6fd7'	System	18 Nov 2020 03:02:24
User entered 'No (N)'	System	18 Nov 2020 03:02:24

**US3482005**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-11-17T22:02:22', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e8eccacb-720e-4a4f-9412-f133ee1e6fd7'	System	18 Nov 2020 03:02:24
User entered '17 Nov 2020 22:02:22'	System	18 Nov 2020 03:02:24

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 20:52:04

US3482005

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:38:36
Data entry locked.	System	10 Aug 2020 20:52:04
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 20:52:04



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-11-20T08:19:57', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd5db1106-2ba9-4cb2-82e3-f4aeae8e9bfb'	System	20 Nov 2020 13:20:21
User entered 'No (N)'	System	20 Nov 2020 13:20:21

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-11-20T08:20:04', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd5db1106-2ba9-4cb2-82e3-f4aeae8e9bfb'	System	20 Nov 2020 13:20:21
User entered 'No (N)'	System	20 Nov 2020 13:20:21

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-11-20T08:20:15', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd5db1106-2ba9-4cb2-82e3-f4aeae8e9bfb'	System	20 Nov 2020 13:20:21
User entered '20 Nov 2020 08:20:15'	System	20 Nov 2020 13:20:21

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-11-25T05:29:00', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1a00b135-d000-4a6b-83eb-ab671377e8b0'	System	25 Nov 2020 10:29:20
User entered 'No (N)'	System	25 Nov 2020 10:29:20



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-11-25T05:29:12', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1a00b135-d000-4a6b-83eb-ab671377e8b0'	System	25 Nov 2020 10:29:20
User entered 'No (N)'	System	25 Nov 2020 10:29:20

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-11-25T05:29:17', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1a00b135-d000-4a6b-83eb-ab671377e8b0'	System	25 Nov 2020 10:29:20
User entered '25 Nov 2020 05:29:17'	System	25 Nov 2020 10:29:20

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-02T06:47:18', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '4291f785-fc53-47bc-849e-22b3f608dd28'	System	02 Dec 2020 11:47:45
User entered 'No (N)'	System	02 Dec 2020 11:47:45

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-02T06:47:26', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '4291f785-fc53-47bc-849e-22b3f608dd28'	System	02 Dec 2020 11:47:45
User entered 'No (N)'	System	02 Dec 2020 11:47:45

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-02T06:47:41', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '4291f785-fc53-47bc-849e-22b3f608dd28' User entered '02 Dec 2020 06:47:41'	System	02 Dec 2020 11:47:45
	System	02 Dec 2020 11:47:45



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-09T12:43:13', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '49c09dbd-5784-47c1-8a7f-de9244fe5c2d'	System	09 Dec 2020 17:43:39
User entered 'No (N)'	System	09 Dec 2020 17:43:39

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-09T12:43:24', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '49c09dbd-5784-47c1-8a7f-de9244fe5c2d'	System	09 Dec 2020 17:43:39
User entered 'No (N)'	System	09 Dec 2020 17:43:39

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-09T12:43:32', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '49c09dbd-5784-47c1-8a7f-de9244fe5c2d' User entered '09 Dec 2020 12:43:32'	System	09 Dec 2020 17:43:39
	System	09 Dec 2020 17:43:39

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-16T09:18:59', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f5f55383-820d-4f8c-a55d-533dcb632e37'	System	16 Dec 2020 14:19:14
User entered 'No (N)'	System	16 Dec 2020 14:19:14

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-16T09:19:05', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f5f55383-820d-4f8c-a55d-533dcb632e37'	System	16 Dec 2020 14:19:14
User entered 'No (N)'	System	16 Dec 2020 14:19:14

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-16T09:19:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'f5f55383-820d-4f8c-a55d-533dcb632e37'	System	16 Dec 2020 14:19:14
User entered '16 Dec 2020 09:19:10'	System	16 Dec 2020 14:19:14

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-23T00:23:03', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '8f258492-5495-43dd-b9f2-380db0b1e142'	System	23 Dec 2020 05:23:27
User entered 'No (N)'	System	23 Dec 2020 05:23:27



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-23T00:23:16', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '8f258492-5495-43dd-b9f2-380db0b1e142'	System	23 Dec 2020 05:23:27
User entered 'No (N)'	System	23 Dec 2020 05:23:27

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-23T00:23:22', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '8f258492-5495-43dd-b9f2-380db0b1e142'	System	23 Dec 2020 05:23:27
User entered '23 Dec 2020 00:23:22'	System	23 Dec 2020 05:23:27

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-30T18:18:04', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'eefdb34e-4b81-4141-b7c7-cd7187ded37a'	System	30 Dec 2020 23:18:41
User entered 'No (N)'	System	30 Dec 2020 23:18:41

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-30T18:18:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'eefdb34e-4b81-4141-b7c7-cd7187ded37a'	System	30 Dec 2020 23:18:41
User entered 'Yes (Y)'	System	30 Dec 2020 23:18:41

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-30T18:18:23', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'eefdb34e-4b81-4141-b7c7-cd7187ded37a'	System	30 Dec 2020 23:18:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 23:18:41



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2020-12-30T18:18:30', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'eefdb34e-4b81-4141-b7c7-cd7187ded37a' User entered '30 Dec 2020 18:18:30'	System	30 Dec 2020 23:18:41
	System	30 Dec 2020 23:18:41

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-07T17:31:20', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '97c5b73a-1466-4e92-9c1c-fcd8bd06c617'	System	07 Jan 2021 22:31:38
User entered 'No (N)'	System	07 Jan 2021 22:31:38

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-07T17:31:25', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '97c5b73a-1466-4e92-9c1c-fcd8bd06c617'	System	07 Jan 2021 22:31:38
User entered 'No (N)'	System	07 Jan 2021 22:31:38

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-07T17:31:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '97c5b73a-1466-4e92-9c1c-fcd8bd06c617'	System	07 Jan 2021 22:31:38
User entered '07 Jan 2021 17:31:35'	System	07 Jan 2021 22:31:38

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-13T07:51:41', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd12b6bbf-8e44-42c3-a81b-71f13f0b091a'	System	13 Jan 2021 12:51:57
User entered 'No (N)'	System	13 Jan 2021 12:51:57

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-13T07:51:49', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd12b6bbf-8e44-42c3-a81b-71f13f0b091a'	System	13 Jan 2021 12:51:57
User entered 'No (N)'	System	13 Jan 2021 12:51:57

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-13T07:51:53', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'd12b6bbf-8e44-42c3-a81b-71f13f0b091a'	System	13 Jan 2021 12:51:57
User entered '13 Jan 2021 07:51:53'	System	13 Jan 2021 12:51:57

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-20T13:26:51', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '63901e3e-5734-4d25-a8c4-36fe25d7c958'	System	20 Jan 2021 18:27:06
User entered 'No (N)'	System	20 Jan 2021 18:27:06

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-20T13:26:56', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '63901e3e-5734-4d25-a8c4-36fe25d7c958'	System	20 Jan 2021 18:27:06
User entered 'No (N)'	System	20 Jan 2021 18:27:06

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-20T13:27:00', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '63901e3e-5734-4d25-a8c4-36fe25d7c958' User entered '20 Jan 2021 13:27:00'	System	20 Jan 2021 18:27:06
	System	20 Jan 2021 18:27:06

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-27T17:34:14', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '19f405fd-adb8-4564-b12f-fb07c60ba037'	System	27 Jan 2021 22:34:28
User entered 'No (N)'	System	27 Jan 2021 22:34:28

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-27T17:34:18', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '19f405fd-adb8-4564-b12f-fb07c60ba037'	System	27 Jan 2021 22:34:28
User entered 'No (N)'	System	27 Jan 2021 22:34:28



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-01-27T17:34:24', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '19f405fd-adb8-4564-b12f-fb07c60ba037'	System	27 Jan 2021 22:34:28
User entered '27 Jan 2021 17:34:24'	System	27 Jan 2021 22:34:28

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-03T04:44:04', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '69216ff0-81db-44bb-8bee-cd489f1a8b47'	System	03 Feb 2021 09:44:20
User entered 'No (N)'	System	03 Feb 2021 09:44:20

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-03T04:44:11', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '69216ff0-81db-44bb-8bee-cd489f1a8b47'	System	03 Feb 2021 09:44:20
User entered 'No (N)'	System	03 Feb 2021 09:44:20

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-03T04:44:16', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '69216ff0-81db-44bb-8bee-cd489f1a8b47'	System	03 Feb 2021 09:44:20
User entered '03 Feb 2021 04:44:16'	System	03 Feb 2021 09:44:20

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-11T18:33:50', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2aca439d-e949-41e0-9df0-02c8697cc0c6'	System	11 Feb 2021 23:34:03
User entered 'No (N)'	System	11 Feb 2021 23:34:03

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-11T18:33:55', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2aca439d-e949-41e0-9df0-02c8697cc0c6'	System	11 Feb 2021 23:34:03
User entered 'No (N)'	System	11 Feb 2021 23:34:03

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-11T18:33:58', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2aca439d-e949-41e0-9df0-02c8697cc0c6'	System	11 Feb 2021 23:34:03
User entered '11 Feb 2021 18:33:58'	System	11 Feb 2021 23:34:03

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-17T20:21:20', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'efa2ed90-d7c3-4fa0-9b01-a41de9f765fc'	System	18 Feb 2021 01:21:41
User entered 'No (N)'	System	18 Feb 2021 01:21:41

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-17T20:21:25', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'efa2ed90-d7c3-4fa0-9b01-a41de9f765fc'	System	18 Feb 2021 01:21:41
User entered 'No (N)'	System	18 Feb 2021 01:21:41

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-17T20:21:36', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'efa2ed90-d7c3-4fa0-9b01-a41de9f765fc' User entered '17 Feb 2021 20:21:36'	System	18 Feb 2021 01:21:41

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-24T02:24:18', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '350c1d0b-ef80-4a20-a86a-f68cc9435707'	System	24 Feb 2021 07:24:32
User entered 'No (N)'	System	24 Feb 2021 07:24:32

US3482005

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:44:17

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-24T02:24:23', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '350c1d0b-ef80-4a20-a86a-f68cc9435707'	System	24 Feb 2021 07:24:32
User entered 'No (N)'	System	24 Feb 2021 07:24:32



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-02-24T02:24:29', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '350c1d0b-ef80-4a20-a86a-f68cc9435707'	System	24 Feb 2021 07:24:32
User entered '24 Feb 2021 02:24:29'	System	24 Feb 2021 07:24:32

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-04T03:40:16', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'dbb71ac9-8b51-4924-b9dc-5c02ae6cfc83'	System	04 Mar 2021 08:40:32
User entered 'No (N)'	System	04 Mar 2021 08:40:32

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-04T03:40:23', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'dbb71ac9-8b51-4924-b9dc-5c02ae6cfc83'	System	04 Mar 2021 08:40:32
User entered 'No (N)'	System	04 Mar 2021 08:40:32

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-04T03:40:30', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'dbb71ac9-8b51-4924-b9dc-5c02ae6cfc83'	System	04 Mar 2021 08:40:32
User entered '04 Mar 2021 03:40:30'	System	04 Mar 2021 08:40:32

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-10T08:15:01', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a26f9e60-4091-4635-8ce9-86c2c01e692a'	System	10 Mar 2021 13:15:16
User entered 'No (N)'	System	10 Mar 2021 13:15:16

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-10T08:15:06', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a26f9e60-4091-4635-8ce9-86c2c01e692a'	System	10 Mar 2021 13:15:16
User entered 'No (N)'	System	10 Mar 2021 13:15:16

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-10T08:15:10', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'a26f9e60-4091-4635-8ce9-86c2c01e692a'	System	10 Mar 2021 13:15:16
User entered '10 Mar 2021 08:15:10'	System	10 Mar 2021 13:15:16

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-17T06:36:35', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'cfdef6de-cb6c-48fa-90c6-f2af38eb6cc1'	System	17 Mar 2021 10:36:55
User entered 'No (N)'	System	17 Mar 2021 10:36:55

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-17T06:36:45', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'cfdef6de-cb6c-48fa-90c6-f2af38eb6cc1'	System	17 Mar 2021 10:36:55
User entered 'No (N)'	System	17 Mar 2021 10:36:55

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-17T06:36:51', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'cfdef6de-cb6c-48fa-90c6-f2af38eb6cc1'	System	17 Mar 2021 10:36:55
User entered '17 Mar 2021 06:36:51'	System	17 Mar 2021 10:36:55

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-09T10:35:54', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2003a014-e9ee-4b76-87da-43420bc014ec'	System	09 Apr 2021 14:36:07
User entered 'No (N)'	System	09 Apr 2021 14:36:07

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-09T10:35:58', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2003a014-e9ee-4b76-87da-43420bc014ec'	System	09 Apr 2021 14:36:07
User entered 'No (N)'	System	09 Apr 2021 14:36:07

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-09T10:36:01', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '2003a014-e9ee-4b76-87da-43420bc014ec'	System	09 Apr 2021 14:36:07
User entered '09 Apr 2021 10:36:01'	System	09 Apr 2021 14:36:07

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-14T10:14:20', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aac3826a-d005-40e2-bb11-f7944eedcaf8'	System	14 Apr 2021 14:15:28
User entered 'Yes (Y)'	System	14 Apr 2021 14:15:28

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-14T10:14:24', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aac3826a-d005-40e2-bb11-f7944eedcaf8'	System	14 Apr 2021 14:15:28
User entered 'No (N)'	System	14 Apr 2021 14:15:28

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-14T10:14:34', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aac3826a-d005-40e2-bb11-f7944eedcaf8'	System	14 Apr 2021 14:15:28
User entered 'No (N)'	System	14 Apr 2021 14:15:28

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-14T10:14:51', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aac3826a-d005-40e2-bb11-f7944eedcaf8'	System	14 Apr 2021 14:15:28
User entered 'Yes (Y)'	System	14 Apr 2021 14:15:28

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-14T10:14:59', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aac3826a-d005-40e2-bb11-f7944eedcaf8'	System	14 Apr 2021 14:15:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Apr 2021 14:15:28

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-14T10:15:09', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'aac3826a-d005-40e2-bb11-f7944eedcaf8'	System	14 Apr 2021 14:15:28
User entered '14 Apr 2021 10:15:09'	System	14 Apr 2021 14:15:28



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-21T08:14:21', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1bb2976b-7fcc-4e15-9b2b-2d2a60e036cb'	System	21 Apr 2021 12:14:36
User entered 'No (N)'	System	21 Apr 2021 12:14:36

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-21T08:14:26', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1bb2976b-7fcc-4e15-9b2b-2d2a60e036cb'	System	21 Apr 2021 12:14:36
User entered 'No (N)'	System	21 Apr 2021 12:14:36

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-21T08:14:30', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: '1bb2976b-7fcc-4e15-9b2b-2d2a60e036cb'	System	21 Apr 2021 12:14:36
User entered '21 Apr 2021 08:14:30'	System	21 Apr 2021 12:14:36

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-30T12:07:15', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'c75c0520-5c49-44bc-a0a4-e540e45fb64c'	System	30 Apr 2021 16:20:23
User entered 'No (N)'	System	30 Apr 2021 16:20:23

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-30T12:07:20', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'c75c0520-5c49-44bc-a0a4-e540e45fb64c'	System	30 Apr 2021 16:20:23
User entered 'No (N)'	System	30 Apr 2021 16:20:23

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-04-30T12:07:24', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'c75c0520-5c49-44bc-a0a4-e540e45fb64c'	System	30 Apr 2021 16:20:23
User entered '30 Apr 2021 12:07:24'	System	30 Apr 2021 16:20:23

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:59:02



**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 02:59:02

**US3482005**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:44:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:59:02
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 02:59:02

US3482005

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:44:17**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-04T03:40:42', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e632f9d1-9491-44dd-95c7-fbc2fcf96cc2'	System	04 Mar 2021 08:40:57
User entered 'No (N)'	System	04 Mar 2021 08:40:57

US3482005

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:44:17

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:09:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a825665267cf8c91)', Time: '2021-03-04T03:40:54', User OID: 'PatientReportedOutcome (US3482005)', ODM File OID: 'e632f9d1-9491-44dd-95c7-fbc2fcf96cc2'	System	04 Mar 2021 08:40:57
User entered '04 Mar 2021 03:40:54'	System	04 Mar 2021 08:40:57

US3482005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Nov 2020 22:43:32

US3482005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '01 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Nov 2020 22:43:32

US3482005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Nov 2020 22:43:32

US3482005

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Nov 2020 22:43:32



US3482005

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Nov 2020 22:43:46

**US3482005**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:44:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:51
User entered 'I'	System	01 Nov 2020 22:43:46

US3482005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:19

US3482005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:19

US3482005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:19

US3482005

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:19

US3482005

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:49:26

**US3482005**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:44:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User entered 'I'	System	07 Dec 2020 15:49:26



US3482005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:35:22

US3482005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:35:22

US3482005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:35:22

US3482005

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:35:22

US3482005

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:35:30

**US3482005**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:44:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User entered 'I'	System	08 Jan 2021 02:35:30

US3482005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:15:11

US3482005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:15:11



US3482005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:15:11

US3482005

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:15:11

US3482005

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:15:18

US3482005

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:54:19
User entered 'I'	System	06 Feb 2021 19:15:18

US3482005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	23 Apr 2021 20:57:33
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:23:56
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Date is correct as written, protocol deviation filed.' (Site from System).	Michelle Wiles (b) (4) (b) (4)	23 Apr 2021 20:57:46
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	23 Apr 2021 20:57:33
User entered '23 Apr 2021'	Michelle Wiles (b) (4) (b) (4)	23 Apr 2021 20:57:33

US3482005

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
User entered 'Clinic (Clinic)'	(b) (4) Michelle Wiles (b) (4)	23 Apr 2021 20:57:33
	(b) (4)	

**US3482005**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:44:17**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	23 Apr 2021 20:57:33



US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	

**US3482005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:52

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	



**US3482005**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:52

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:52

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:52

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:52
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:52

US3482005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	23 Apr 2021 20:57:57
	(b) (4)	



US3482005

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:57
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	23 Apr 2021 20:58:16
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered '23 Apr 2021'	Michelle Wiles (b) (4)	23 Apr 2021 20:58:16
	(b) (4)	

US3482005

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered '10:27'	Michelle Wiles (b) (4)	23 Apr 2021 20:58:16
	(b) (4)	

**US3482005**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:44:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Apr 2021 10:27'	System	23 Apr 2021 20:58:16

US3482005

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:16:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 15:25:08

**US3482005**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:44:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 15:25:08

US3482005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:05
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:16:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 15:25:41



US3482005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:05
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:16:51
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:25:41

US3482005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:05
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:16:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:25:41

US3482005

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:05
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:16:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:25:41

US3482005

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:05
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:25:48

US3482005

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:27:05
User entered 'I'	System	07 Apr 2021 15:25:48

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:17

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:58:04
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:09:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:17

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:58:04
User entered '13:05'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:09:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:17

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:46
User entered '08 Jan 2021 13:05'	System	08 Jan 2021 21:09:33



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:17

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:58:04
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:09:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:44:17

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:46
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 19:58:04
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:09:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User closed query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 08 Jan 2021 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).		26 Apr 2021 15:24:36
Query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 08 Jan 2021 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 'Source completed' (Site from DM).	Joy Winters (b) (4) (b) (4)	20 Apr 2021 18:25:42
User opened query 'Per CDM: Please verify that Symptom Log Line 1 in Covid-19 Assessment 08 Jan 2021 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 10:15:20
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 1 (Day 1)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:20:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '26 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:20:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:02:41
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:33:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:00:09
User entered '1' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:37
DataPoint Un-verified.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered '0' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:20:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:00:15
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:20:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:25:30
User entered empty.	System	08 Jan 2021 21:20:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:00:17
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty; reason for change Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 21:24:38
User entered '99.8' F	Joy Winters (b) (4)	08 Jan 2021 21:20:27



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:00:32
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:20:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:00:37
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	(b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	
	Joy Winters (b) (4)	08 Jan 2021 21:20:27
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:00:40
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	(b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:20:27
	Joy Winters (b) (4)	
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:00:42
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:20:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:00:44
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:20:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:00:46
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:20:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:00:49
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	(b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:20:27
	Joy Winters (b) (4)	
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:20:27



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 22:02:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:00:52
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	(b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	(b) (4)
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
	Joy Winters (b) (4)	08 Jan 2021 21:20:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:00:55
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:20:27

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:00:57
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	(b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:20:27
	Joy Winters (b) (4)	
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:01:06
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	(b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	
	Joy Winters (b) (4)	08 Jan 2021 21:20:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:01:08
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	(b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:20:27
	Joy Winters (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:01:10
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:20:27

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:01:13
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:20:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:01:16
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:25:30
Signature has been broken.	(b) (4)	20 Apr 2021 18:25:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:25:30
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:20:27
	Joy Winters (b) (4)	
	(b) (4)	



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User closed query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 08 Jan 2021 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)	26 Apr 2021 15:24:40
Query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 08 Jan 2021 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 'source documentation updated' (Site from DM).	Joy Winters (b) (4) (b) (4)	20 Apr 2021 18:26:58
User opened query 'Per CDM: Please verify that Symptom Log Line 2 in Covid-19 Assessment 08 Jan 2021 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 10:15:33
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 2 (Day 2)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '27 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:02:48
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:33:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:01:32
User entered '1' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:37
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered '0' reason for change: Data Entry Error	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:21:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:01:34
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
User entered missing code ND - Not Done; reason for	Joy Winters (b) (4)	20 Apr 2021 18:27:02
change Data Entry Error	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:21:33
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:27:02
User entered empty.	System	08 Jan 2021 21:21:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 01:15:38
User closed query 'Per source, patients temp was ranging from 99.6. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 01:15:35
Query 'Per source, patients temp was ranging from 99.6. Please confirm and update.' answered with 'Updated and confirmed. 06MAR2021 JCW ' (Site from CRA).	Joy Winters (b) (4) (b) (4)	06 Mar 2021 13:39:17
User entered '99.6' F reason for change: Data Entry Error	Joy Winters (b) (4) (b) (4)	06 Mar 2021 13:37:53
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:33:58
User opened query 'Per source, patients temp was ranging from 99.6. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 20:05:36
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '99.8' F	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:21:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:21:33
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:21:33
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:39:44
DataPoint Un-verified.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:21:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:21:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:21:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
Signature has been broken.	(b) (4)	20 Apr 2021 18:27:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	
	Joy Winters (b) (4)	08 Jan 2021 21:21:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:27:02
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:27:02
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:21:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User closed query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 08 Jan 2021 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)	26 Apr 2021 15:24:46
Query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 08 Jan 2021 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 'source documentation updated' (Site from DM).	Joy Winters (b) (4) (b) (4)	20 Apr 2021 18:30:11
User opened query 'Per CDM: Please verify that Symptom Log Line 3 in Covid-19 Assessment 08 Jan 2021 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 10:15:44
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 3 (Day 3)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:25:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '28 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:25:33



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:02:57
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:33:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:07:09
User entered '1' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:37
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered '0' reason for change: Data Entry Error	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:29:49
User entered empty.	System	08 Jan 2021 21:25:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:07:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:33:42
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '100.1' F	Joy Winters (b) (4)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
	(b) (4)	
Signature has been broken.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:25:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	
	Joy Winters (b) (4)	08 Jan 2021 21:25:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:25:33

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:25:33



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	
	Joy Winters (b) (4)	08 Jan 2021 21:25:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:39:44
DataPoint Un-verified.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:25:33
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:25:33



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	
	Joy Winters (b) (4)	08 Jan 2021 21:25:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:25:33

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:29:49
Signature has been broken.	(b) (4)	20 Apr 2021 18:29:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:29:49
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	
	Joy Winters (b) (4)	08 Jan 2021 21:25:33
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User closed query 'Per CDM: Please verify that Symptom Log Line 4 in Covid-19 Assessment 08 Jan 2021 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)	26 Apr 2021 15:24:51
Query 'Per CDM: Please verify that Symptom Log Line 4 in Covid-19 Assessment 08 Jan 2021 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 'source documentation updated' (Site from DM).	Joy Winters (b) (4) (b) (4)	20 Apr 2021 18:31:40
User opened query 'Per CDM: Please verify that Symptom Log Line 4 in Covid-19 Assessment 08 Jan 2021 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 10:15:54
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 4 (Day 4)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '29 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:03:03
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:33:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:07:09
User entered '1' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:37
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered '0' reason for change: Data Entry Error	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
User entered missing code ND - Not Done; reason for	Joy Winters (b) (4)	20 Apr 2021 18:31:35
change Data Entry Error	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:26:28
	(b) (4)	



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:31:35
User entered empty.	System	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:07:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '100.4' F	Joy Winters (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:26:28
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:26:28
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:26:28
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:39:44
DataPoint Un-verified.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:26:28
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'Mild (Mild)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Form: Symptom Log (4)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:26:28
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:31:35
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:31:35
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:26:28

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User closed query 'Per CDM: Please verify that Symptom Log Line 5 in Covid-19 Assessment 08 Jan 2021 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)	26 Apr 2021 15:24:55
Query 'Per CDM: Please verify that Symptom Log Line 5 in Covid-19 Assessment 08 Jan 2021 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 'source documentation updated' (Site from DM).	Joy Winters (b) (4) (b) (4)	20 Apr 2021 18:33:15
User opened query 'Per CDM: Please verify that Symptom Log Line 5 in Covid-19 Assessment 08 Jan 2021 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 10:16:05
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 5 (Day 5)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '30 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:33:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:07:09
User entered '1' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:37
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered '0' reason for change: Data Entry Error	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:27:21

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Form: Symptom Log (5)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:27:21

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Form: Symptom Log (5)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:33:17
User entered empty.	System	08 Jan 2021 21:27:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:07:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:19
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '99.7' F	Joy Winters (b) (4)	08 Jan 2021 21:27:21



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:27:21
	(b) (4)	

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Form: Symptom Log (5)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:27:21
	Joy Winters (b) (4)	
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:27:21
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:27:21

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:39:44
DataPoint Un-verified.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:27:21
	Joy Winters (b) (4)	
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:27:21
	Joy Winters (b) (4)	
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 21:28:51
User entered 'Mild (Mild)'	(b) (4) Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:27:21

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:27:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:33:17
Signature has been broken.	(b) (4)	20 Apr 2021 18:33:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:33:17
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:27:21
	Joy Winters (b) (4)	
	(b) (4)	



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User closed query 'Per CDM: Please verify that Symptom Log Line 6 in Covid-19 Assessment 08 Jan 2021 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)	26 Apr 2021 15:24:59
Query 'Per CDM: Please verify that Symptom Log Line 6 in Covid-19 Assessment 08 Jan 2021 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 'source documentation updated' (Site from DM).	Joy Winters (b) (4) (b) (4)	20 Apr 2021 18:34:46
User opened query 'Per CDM: Please verify that Symptom Log Line 6 in Covid-19 Assessment 08 Jan 2021 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 10:16:16
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 6 (Day 6)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:28:02

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '31 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:28:02

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:33:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:33:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:07:09
User entered '1' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
DataPoint Un-verified.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
Signature has been broken.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered '0' reason for change: Data Entry Error	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:28:02

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:34:39
User entered empty.	System	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:07:09
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:29
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '98.8' F	Joy Winters (b) (4)	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 22:07:09
Signature has been broken.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:34:54
User signature succeeded.	Michelle Wiles (b) (4)	20 Apr 2021 15:34:54
DataPoint Verified.	(b) (4)	20 Apr 2021 15:34:54
User entered empty.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	04 Feb 2021 20:04:41
	(b) (4), (b) (6)	04 Feb 2021 20:04:41
	Joy Winters (b) (4)	08 Jan 2021 21:28:02
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:28:02
	(b) (4)	



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:28:02
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	(b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:28:02

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:28:02

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:28:02

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:39:44
DataPoint Un-verified.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	(b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:28:02



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	(b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 21:28:35
User entered 'Mild (Mild)'	(b) (4) Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:28:02
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:28:02
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	(b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:34:39
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:34:39
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:28:02

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 7 (Day 7)'	Joy Winters (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '01 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:24



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:38:54
User entered empty.	System	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:29:24
	Joy Winters (b) (4)	
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:24



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4)	20 Apr 2021 18:38:54
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:24
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:24
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:24



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Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:29:24
	Joy Winters (b) (4)	
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:29:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:24
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:38:54
Signature has been broken.	(b) (4)	20 Apr 2021 18:38:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:38:54
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	
	Joy Winters (b) (4)	08 Jan 2021 21:29:24
	(b) (4)	

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Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 8 (Day 8)'	Joy Winters (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '02 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:41:00
User entered empty.	System	08 Jan 2021 21:29:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
	(b) (4)	
User entered missing code ND - Not Done; reason for	Joy Winters (b) (4)	20 Apr 2021 18:41:00
change Data Entry Error	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	(b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:29:51
	Joy Winters (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51
	(b) (4)	



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	(b) (4)	20 Apr 2021 18:41:00
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	(b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:29:51
	Joy Winters (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	(b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:29:51
	Joy Winters (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51
	(b) (4)	



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:41:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:29:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 9 (Day 9)'	Joy Winters (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '03 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:47:13
User entered empty.	System	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:24



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:24
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:30:24



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 10 (Day 10)'	Joy Winters (b) (4)	08 Jan 2021 21:30:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '04 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:30:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:47:13
User entered empty.	System	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:59



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:59
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:59



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:59
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:59
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:30:59
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	Nadine Rouphael (b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 21:30:59

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 11 (Day 11)'	Joy Winters (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '05 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered missing code ND - Not Done; reason for	Joy Winters (b) (4)	20 Apr 2021 18:47:13
change Data Entry Error	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46
	(b) (4)	

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:47:13
User entered empty.	System	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 12 (Day 12)'	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '06 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:47:13
User entered empty.	System	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46



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Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46



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Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Form: Symptom Log (13)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 13 (Day 13)'	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '07 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:06
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:34:45
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '1'	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	20 Apr 2021 18:47:13
User entered empty.	System	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	(b) (4), (b) (6)	
	Joy Winters (b) (4)	08 Jan 2021 21:32:46
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46



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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
	(b) (4)	
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'None (None)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:32:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:07:09
DataPoint Un-verified.	Joy Winters (b) (4)	20 Apr 2021 18:47:13
Signature has been broken.	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Joy Winters (b) (4)	20 Apr 2021 18:47:13
User signature succeeded.	(b) (4) Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:32:46



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 14 (Day 14)'	Joy Winters (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '95'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '98.3' F	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:35:08

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 15 (Day 15)'	(b) (4) Michelle Wiles (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	09 Jan 2021 20:16:31
User entered '09 Jan 2021' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:16:31
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	09 Jan 2021 20:15:09
User entered '10 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '92' reason for change: Data Entry Error	Michelle Wiles (b) (4)	09 Jan 2021 20:25:50
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	09 Jan 2021 20:25:50
User entered empty.	System	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '99.1' F reason for change: Data Entry Error	Michelle Wiles (b) (4)	09 Jan 2021 20:19:38
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	09 Jan 2021 20:15:09

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 16 (Day 16)'	(b) (4) Michelle Wiles (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '10 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '99'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '97.5' F	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	11 Jan 2021 19:11:34
User entered 'Mild (Mild)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	10 Jan 2021 17:09:38

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 17 (Day 17)'	(b) (4) Michelle Wiles (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '11 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:47:00
Query 'Per source, the O2 Sat on this date was 94%. Please confirm and update.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 20:46:58
User opened query 'Per source, the O2 Sat on this date was 94%. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 20:45:38
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:30
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '97'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '97.7' F	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	11 Jan 2021 19:09:42



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 18 (Day 18)'	(b) (4) Michelle Wiles (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '12 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '94'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '97.7' F	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	12 Jan 2021 18:56:43

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 19 (Day 19)'	(b) (4) Michelle Wiles (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '13 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '97' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	14 Jan 2021 14:19:58
User entered empty.	System	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '97.6' F reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	14 Jan 2021 14:19:58
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	13 Jan 2021 20:43:53

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 08 Jan 2021 symptom log on log line 20. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 15:25:09
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 08 Jan 2021 symptom log on log line 20. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'Missing data not available, please see source doc, protocol deviation filed.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	20 Apr 2021 18:55:25
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 08 Jan 2021 symptom log on log line 20. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:16:38
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 20 (Day 20)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '14 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered empty.	System	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 21:26:27

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 21 (Day 21)'	Michelle Wiles (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '15 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '93' reason for change: Data Entry Error	Michelle Wiles (b) (4)	15 Jan 2021 22:30:11
User entered empty.	(b) (4) Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	15 Jan 2021 22:30:11
User entered empty.	System	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '98.4' F	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	15 Jan 2021 22:20:46



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 22 (Day 22)'	(b) (4) Lauren Hewitt (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '16 Jan 2021'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered missing code ND - Not Done.	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered missing code ND - Not Done.	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Lauren Hewitt (b) (4) (b) (4)	17 Jan 2021 22:54:51

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 23 (Day 23)'	(b) (4) Michelle Wiles (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '17 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'I'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered empty.	System	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered empty.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:25:04

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 24 (Day 24)'	(b) (4) Michelle Wiles (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '18 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered missing code ND - Not Done.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered missing code ND - Not Done.	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	19 Jan 2021 20:26:32
User entered 'Mild (Mild)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:26:24

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 25 (Day 25)'	(b) (4) Michelle Wiles (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '19 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '99'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '97.7' F	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:30:47



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 26 (Day 26)'	(b) (4) Michelle Wiles (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '20 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '99'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '98.9' F	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:57:01

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 27 (Day 27)'	(b) (4) Michelle Wiles (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '21 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '98'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '99.1' F	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'Mild (Mild)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:58:10

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Day 28 (Day 28)'	(b) (4) Michelle Wiles (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '22 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '0'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '100'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User entered '%'	System	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered '98.5' F	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:44:17

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:52
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:04:41
User entered 'None (None)'	Michelle Wiles (b) (4) (b) (4)	22 Jan 2021 20:59:19

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:49:39
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:10:12

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:49:39
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:10:12

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:49:39
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)	02 Feb 2021 16:14:52
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 'HAS AE FOR COVID ENTERED ALREADY.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 16:36:22
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 00:04:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 00:04:25
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	19 Jan 2021 00:04:25
User entered 'Yes (Y)' reason for change: New Information	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 00:04:25
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 21:10:12
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:10:12

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:49:39
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:10:12

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:49:39
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:10:12

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:49:39
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:10:12



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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:49:39
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:10:12

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:49:39
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:10:12

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:49:39
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:10:12

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:44:17

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:55
User entered 'I'	System	19 Jan 2021 00:04:25

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 19:09:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 19:09:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:09:02
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 19:08:54
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered '09 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 21 (15Jan2021), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:23:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:05:37
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 21 (15Jan2021), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' answered with 'Correction made to correct error.' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	21 Apr 2021 13:40:07
DataPoint Un-verified.	Michelle Wiles (b) (4) (b) (4)	21 Apr 2021 13:39:19
Signature has been broken.	Michelle Wiles (b) (4) (b) (4)	21 Apr 2021 13:39:19
User entered '15 Jan 2021' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	21 Apr 2021 13:39:19
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 21 (15Jan2021), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:46:24
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered '09 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered '92'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54



US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:44:17

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:08:59
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:08:54

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:46



US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Michelle Wiles (b) (4)	22 Mar 2021 16:45:33
User entered 'Yes (Y)'	(b) (4)	
	Michelle Wiles (b) (4)	04 Feb 2021 19:00:46
	(b) (4)	

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:44:17

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User closed query 'Per GCL Lab Recon: SALIVA: Day 3 SALIVA sample with collection date of "10 JAN 2021", is missing in PPD GCL, as per Preclarus report. Please kindly review if the sample has been collected and shipped, and if shipped kindly provide Accession number, air way bill number and shipping date in the response. If sample has been received at PPD GCL please kindly update in Preclarus and confirm in the response Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 09:54:50
Query 'Per GCL Lab Recon: SALIVA: Day 3 SALIVA sample with collection date of "10 JAN 2021", is missing in PPD GCL, as per Preclarus report. Please kindly review if the sample has been collected and shipped, and if shipped kindly provide Accession number, air way bill number and shipping date in the response. If sample has been received at PPD GCL please kindly update in Preclarus and confirm in the response Thank you. ' answered with 'Sample not collected, PD filed' (Site from DM).	Michelle Wiles (b) (4) (b) (4)	22 Mar 2021 16:45:45
User entered empty; reason for change Data Entry Error	Michelle Wiles (b) (4) (b) (4)	22 Mar 2021 16:45:33
User opened query 'Per GCL Lab Recon: SALIVA: Day 3 SALIVA sample with collection date of "10 JAN 2021", is missing in PPD GCL, as per Preclarus report. Please kindly review if the sample has been collected and shipped, and if shipped kindly provide Accession number, air way bill number and shipping date in the response. If sample has been received at PPD GCL please kindly update in Preclarus and confirm in the response Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 20:05:01
User entered '10 Jan 2021'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:44:17

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:44:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

**US3482005**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:44:17**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '14 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46



US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:44:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

**US3482005**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:44:17**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '16 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:44:17

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '21 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

**US3482005**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:44:17**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:44:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46



**US3482005**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:44:17**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '28 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:17

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:44:17

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

**US3482005**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:44:17**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '04 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:00:46

US3482005

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:30
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:07:15

US3482005

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:30
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:07:15

US3482005

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[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 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:50:30
User entered 'Clinic (Clinic)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:07:15

US3482005

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User entered 'SICKD1'	System	08 Jan 2021 21:07:15



US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered '13:11'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User entered '08 Jan 2021 13:11'	System	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered missing code ND - Not Done.	Joy Winters (b) (4)	08 Jan 2021 21:08:23
DataPoint set to visible.	(b) (4) System	08 Jan 2021 21:07:15

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered missing code ND - Not Done.	Joy Winters (b) (4)	08 Jan 2021 21:08:23
DataPoint set to visible.	(b) (4) System	08 Jan 2021 21:07:15

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered '98.3' F	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered 'Oral (Oral)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23



US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered '80'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23

**US3482005**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User entered 'bpm'	System	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered '16'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User entered 'breaths/min'	System	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered '142'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User entered 'mmHg'	System	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:41
User entered '66'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:23



US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User entered 'mmHg'	System	08 Jan 2021 21:08:23

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26

US3482005

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26

US3482005

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:49
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:39

US3482005

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:52:49
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:39

US3482005

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:44:17

[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 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:53:01
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:59

US3482005

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:44:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:03:26
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:53:01
User entered '08 Jan 2021'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:08:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:53:39
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:59



US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:53:39
User entered '04 Feb 2021'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[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 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:53:39
User entered 'Clinic (Clinic)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:00:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User entered 'SICKD28'	System	04 Feb 2021 19:00:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered '04 Feb 2021'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered '12:39'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User entered '04 Feb 2021 12:39'	System	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered missing code ND - Not Done.	Michelle Wiles (b) (4)	04 Feb 2021 19:02:59
DataPoint set to visible.	(b) (4) System	04 Feb 2021 19:00:59



US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered missing code ND - Not Done.	Michelle Wiles (b) (4)	04 Feb 2021 19:02:59
DataPoint set to visible.	(b) (4) System	04 Feb 2021 19:00:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered '98.0' F	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered 'Oral (Oral)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered empty.	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered '66'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User entered 'bpm'	System	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered '16'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User entered 'breaths/min'	System	04 Feb 2021 19:02:59



US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered '144'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User entered 'mmHg'	System	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:58:18
User entered '65'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User entered 'mmHg'	System	04 Feb 2021 19:02:59

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:07:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User closed query 'Per CDM: Convalescence visit and Participant Decision visit / OL-D1 are both dated 04Feb2021, however, 'Was the physical examination performed?' is NO at Convalescence visit but at OL-D1 'Was the physical examination performed?' is YES and data is present. If the visits occurred on the same day, then the examination data should be entered at both visits per sponsor. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:01:34
Query 'Per CDM: Convalescence visit and Participant Decision visit / OL-D1 are both dated 04Feb2021, however, 'Was the physical examination performed?' is NO at Convalescence visit but at OL-D1 'Was the physical examination performed?' is YES and data is present. If the visits occurred on the same day, then the examination data should be entered at both visits per sponsor. Please review and update as appropriate. ' answered with 'DONE' (Site from DM).	Mari Hart (b) (4) (b) (4)	30 Mar 2021 18:47:06
DataPoint Un-verified.	Mari Hart (b) (4)	30 Mar 2021 18:46:59
Signature has been broken.	(b) (4) Mari Hart (b) (4)	30 Mar 2021 18:46:59
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4) Mari Hart (b) (4)	30 Mar 2021 18:46:59
User opened query 'Per CDM: Convalescence visit and Participant Decision visit / OL-D1 are both dated 04Feb2021, however, 'Was the physical examination performed?' is NO at Convalescence visit but at OL-D1 'Was the physical examination performed?' is YES and data is present. If the visits occurred on the same day, then the examination data should be entered at both visits per sponsor. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 05:18:14
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:17:22

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EAB) (1725)

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US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:58:27
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:01:08



US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:07:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Un-verified.	(b) (4)	
	Mari Hart (b) (4)	30 Mar 2021 18:46:59
Signature has been broken.	(b) (4)	
	Mari Hart (b) (4)	30 Mar 2021 18:46:59
User entered '04 Feb 2021' reason for change: Per Query Resolution	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:58:27
User entered empty.		
	Michelle Wiles (b) (4)	04 Feb 2021 19:01:08
	(b) (4)	

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:44:17

[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 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:59:01
User entered 'Yes (Y)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:01:56

US3482005

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:44:17

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:09:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:59:01
User entered '04 Feb 2021'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:01:56

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:04:14

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '04 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:04:14

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Clinic (Clinic)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:04:14

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 19:04:14

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '06 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:06:19



**US3482005**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:44:17**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:06:54

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:06:54

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '04 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Placebo (Placebo)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Placebo (Placebo)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Placebo (Placebo)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:06:19



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'I'	System	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:44:17

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'I'	System	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered empty.	System	04 Feb 2021 19:09:11
DataPoint set to visible.	System	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered empty.	System	04 Feb 2021 19:09:11
DataPoint set to visible.	System	04 Feb 2021 19:06:19



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User accepted default value 'Pre-Dose (PREDOSE)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '04 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12:39'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered '04 Feb 2021 12:39'	System	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '98.0' F	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Oral (Oral)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '66'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'bpm'	System	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '16'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'breaths/min'	System	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '144'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'mmHg'	System	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '65'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'mmHg'	System	04 Feb 2021 19:09:11



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:44:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered empty.	System	04 Feb 2021 19:09:11
DataPoint set to visible.	System	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User accepted default value 'Post-Dose (POSTDOSE)'	Michelle Wiles (b) (4) (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '04 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '13:48'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered '04 Feb 2021 13:48'	System	04 Feb 2021 19:09:11



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '97.3' F	Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Oral (Oral)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '90'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'bpm'	System	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '16'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'breaths/min'	System	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '130'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'mmHg'	System	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '64'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'mmHg'	System	04 Feb 2021 19:09:11

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:06:29

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '04 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:06:29

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:07

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:07

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	Michelle Wiles (b) (4)	04 Feb 2021 19:07:07



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'mRNA-1273'	System	04 Feb 2021 19:07:07
DataPoint set to visible.	System	04 Feb 2021 19:06:19

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '04 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:07

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '13:16'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:07

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered '04 Feb 2021 13:16'	System	04 Feb 2021 19:07:07

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:07

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'ONCE'	System	04 Feb 2021 19:07:07

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 19:07:07

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:47



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '04 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:47

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12:16'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:47

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered '04 Feb 2021 12:16'	System	04 Feb 2021 19:07:47

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:59

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '04 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:59

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12:21'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:07:59

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:44:17

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered '04 Feb 2021 12:21'	System	04 Feb 2021 19:07:59

US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	04 Feb 2021 19:08:04



US3482005

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:05
User entered 'I'	System	04 Feb 2021 19:08:04

**US3482005**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:44:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	12 Feb 2021 19:16:46

US3482005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12 Feb 2021'	(b) (4) Michelle Wiles (b) (4)	12 Feb 2021 19:16:46

US3482005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michelle Wiles (b) (4)	12 Feb 2021 19:16:46

US3482005

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) Michelle Wiles (b) (4)	12 Feb 2021 19:16:46

US3482005

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	12 Feb 2021 19:17:20

**US3482005**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:44:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:00
User entered 'I'	System	12 Feb 2021 19:17:20

**US3482005**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:44:17**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:52:00
User entered '1'	System	12 Feb 2021 19:17:20
DataPoint set to visible.	System	12 Feb 2021 19:17:20



US3482005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:51:55

US3482005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12 Mar 2021'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:51:55

US3482005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Clinic (Clinic)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:51:55

US3482005

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'OLD29'	System	12 Mar 2021 15:51:55

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Hewitt (b) (4) (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12 Mar 2021'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

**US3482005**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:44:17**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '08:55'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18



US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered '12 Mar 2021 08:55'	System	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '97.5' F	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Oral (Oral)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '82'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'bpm'	System	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '16'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'breaths/min'	System	12 Mar 2021 15:53:18



US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '133'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'mmHg'	System	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '65'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'mmHg'	System	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Hewitt (b) (4) (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12 Mar 2021'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '10:29'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18



US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered '12 Mar 2021 10:29'	System	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '98.0' F	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Oral (Oral)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '74'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'bpm'	System	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '16'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'breaths/min'	System	12 Mar 2021 15:53:18



US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '143'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'mmHg'	System	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '64'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:44:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'mmHg'	System	12 Mar 2021 15:53:18

US3482005

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:27

US3482005

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12 Mar 2021'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:27

US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:48

US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:48



US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:48

US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'mRNA-1273'	System	12 Mar 2021 15:53:48
DataPoint set to visible.	System	12 Feb 2021 19:17:20

US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '12 Mar 2021'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:48

US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '09:50'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:48

US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered '12 Mar 2021 09:50'	System	12 Mar 2021 15:53:48

US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:48

US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'ONCE'	System	12 Mar 2021 15:53:48

US3482005

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:44:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'INTRAMUSCULAR'	System	12 Mar 2021 15:53:48



US3482005

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:53:54

**US3482005**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:44:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:48:37
User entered 'I'	System	12 Mar 2021 15:53:54

**US3482005**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:44:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	22 Mar 2021 17:09:00

**US3482005**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:44:17**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '22 Mar 2021'	Michelle Wiles (b) (4)	22 Mar 2021 17:09:00

US3482005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michelle Wiles (b) (4)	22 Mar 2021 17:09:00

US3482005

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:44:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered empty.	(b) (4) Michelle Wiles (b) (4)	22 Mar 2021 17:09:00

US3482005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	22 Mar 2021 17:09:21

US3482005

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:44:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:16
User entered 'I'	System	22 Mar 2021 17:09:21



**US3482005**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:44:17**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	23 Apr 2021 20:56:57
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:44:17**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered '23 Apr 2021'	Michelle Wiles (b) (4)	23 Apr 2021 20:56:57
	(b) (4)	

US3482005

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:44:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'Clinic (Clinic)'	Michelle Wiles (b) (4)	23 Apr 2021 20:56:57
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:44:17**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	23 Apr 2021 20:56:57

**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	

US3482005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:03



US3482005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:03

US3482005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	

US3482005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:03

**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
User entered empty.	(b) (4) Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	



**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:03

US3482005

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:44:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
User entered empty.	(b) (4) Michelle Wiles (b) (4)	23 Apr 2021 20:57:03
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:44:17**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 20:57:03

US3482005

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:44:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	23 Apr 2021 20:57:07
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:44:17**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 20:57:07
	(b) (4)	

US3482005

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:44:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	23 Apr 2021 20:57:21
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:44:17**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered '23 Apr 2021'	Michelle Wiles (b) (4)	23 Apr 2021 20:57:21
	(b) (4)	

**US3482005**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:44:17**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered '10:27'	Michelle Wiles (b) (4)	23 Apr 2021 20:57:21
	(b) (4)	



**US3482005**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:44:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Apr 2021 10:27'	System	23 Apr 2021 20:57:21

US3482005

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:44:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:07:01
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:15
User entered 'Yes (Y)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:36:27

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:04
User entered		
'USA-US106-2021-mRNA-1273-P301000006'	System	21 Jan 2021 18:29:42
User entered 'New'	(b) (4), (b) (6)	21 Jan 2021 18:29:42

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
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 Jan 2021 20:21:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Jan 2021 20:21:09
Data point term sent to Coder	System	19 Jan 2021 20:20:14
Coding entries removed.	Michelle Wiles (b) (4)	19 Jan 2021 20:19:35
	(b) (4)	
User entered 'COVID-19' reason for change: Data Entry Error	Michelle Wiles (b) (4)	19 Jan 2021 20:19:35
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Influenza like illness, LLT: Flu-like illness - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 21:41:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 21:41:43
	(b) (4)	
Data point term sent to Coder	System	08 Jan 2021 21:41:22
User entered 'Flu-like illness'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	20 Jan 2021 19:06:11
	(b) (4)	
User entered 'No (N)'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:40:46

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	20 Jan 2021 19:06:11
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:40:46

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
User closed query 'PV Query: The start date of the event is 26 Dec 2020. Did the subject report any symptoms on that day? If yes, please update the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:39
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:08:20
Query 'PV Query: The start date of the event is 26 Dec 2020. Did the subject report any symptoms on that day? If yes, please update the COVID-19 assessment symptom log in EDC.' answered with 'SYMPTOM LOG SHOWS HEADACHE.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 17:42:41
User opened query 'PV Query: The start date of the event is 26 Dec 2020. Did the subject report any symptoms on that day? If yes, please update the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 16:34:19
User entered '26 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:40:46



US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

**US3482005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:44:17**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 21:40:46

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	29 Jan 2021 22:50:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Wiles (b) (4)	19 Jan 2021 20:19:58
User entered 'No (N)'	(b) (4)	
	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:21:16
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
DataPoint Un-verified.	Joy Winters (b) (4)	29 Mar 2021 18:09:40
Signature has been broken.	Joy Winters (b) (4)	29 Mar 2021 18:09:40
User entered '23 Jan 2021' reason for change: New Information	Joy Winters (b) (4)	29 Mar 2021 18:09:40
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered '21 Jan 2021' reason for change: New Information	Michelle Wiles (b) (4)	04 Feb 2021 18:59:13
User entered '22 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	29 Jan 2021 22:50:06
User entered empty; reason for change Data Entry Error	Michelle Wiles (b) (4)	19 Jan 2021 20:19:58
User entered '29 Dec 2020'	Joy Winters (b) (4)	08 Jan 2021 21:40:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:40:46

**US3482005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:44:17**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 21:40:46

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	Michelle Wiles (b) (4)	04 Feb 2021 18:59:19
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'No (N)'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered '0'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:40:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'Not Related (NOT RELATED)'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'Not Applicable (NOT APPLICABLE)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:40:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:08:20
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 15:56:38
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'OTC COLD MEDS AND AIRBORNE TAKEN FOR UPPER RESPIRATORY SYMPTOMS, BEFORE PPT KNEW IT WAS COVID. SEE CON MEDS.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 22:41:29
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:37:12
User entered 'I'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:40:46

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered '0'	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	29 Jan 2021 22:50:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Michelle Wiles (b) (4) (b) (4)	19 Jan 2021 20:19:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:40:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered empty.	Joy Winters (b) (4)	08 Jan 2021 21:40:46
	(b) (4)	

US3482005

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:44:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:21:21
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User closed query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 21 Jan 2021; however, symptoms were still reported on 21 Jan 2021.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:57:09
' (Site from Safety). Query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 21 Jan 2021; however, symptoms were still reported on 21 Jan 2021.	Joy Winters (b) (4) (b) (4)	29 Mar 2021 18:13:05
' answered with 'Updated and resolved.' (Site from Safety).		
DataPoint Un-verified.	Joy Winters (b) (4)	29 Mar 2021 18:12:41
Signature has been broken.	(b) (4) Joy Winters (b) (4)	29 Mar 2021 18:12:41
User entered 'The stop date of symptoms is 23JAN2021. We have updated after clarifying with subject. The ecrf is also updated.' reason for change: Data Entry Error	(b) (4)	29 Mar 2021 18:12:41
User opened query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 21 Jan 2021; however, symptoms were still reported on 21 Jan 2021.	(b) (4), (b) (6)	26 Mar 2021 19:28:38
' (Site from Safety). User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:08:20
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:40:46

**US3482005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:44:17**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Jan 2021 21:40:46

**US3482005**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:44:17**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 19:06:11
User entered '0'	System	08 Jan 2021 21:40:46

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	23 Apr 2021 03:22:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:26:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of legs - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 21:42:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 21:42:34
Data point term sent to Coder	System	19 Apr 2021 15:35:31
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event "BILATERAL FOOT AND ANKLE SWELLING(LEFT >RIGHT)" or split to report each event separately to capture coding for all terms. Example: 1) BILATERAL FOOT SWELLING (LEFT >RIGHT)2) BILATERAL ANKLE SWELLING (LEFT >RIGHT). Thank you. ' (Site from System).	System	19 Apr 2021 15:35:27
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event "BILATERAL FOOT AND ANKLE SWELLING(LEFT >RIGHT)" or split to report each event separately to capture coding for all terms. Example: 1) BILATERAL FOOT SWELLING (LEFT >RIGHT)2) BILATERAL ANKLE SWELLING (LEFT >RIGHT). Thank you. ' answered with 'UPDATED . SEE NARRATIVE FOR ADDITIONAL CLARIFICATION.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 15:35:27
User entered 'BILATERAL LOWER EXTREMITY SWELLING (LEFT >RIGHT)' reason for change: Per Query Resolution	(b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 15:35:05
Data point term sent to Coder	System	19 Apr 2021 15:34:29
Signature has been broken.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 15:34:02
User entered 'BILATERAL LOWER EXTREMITY SWELLING (LEFT >RIGHT).' reason for change: Per Query Resolution	(b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 15:34:02

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event "BILATERAL FOOT AND ANKLE SWELLING(LEFT &gt;RIGHT)" or split to report each event separately to capture coding for all terms. Example: 1) BILATERAL FOOT SWELLING (LEFT &gt;RIGHT)2) BILATERAL ANKLE SWELLING (LEFT &gt;RIGHT). Thank you. ' (Site from System). User signature succeeded.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:55:24
Data point term sent to Coder Coding entries removed.	Nadine Rouphael (b) (4) (b) (4) System	17 Apr 2021 03:07:55 14 Apr 2021 17:27:29
User entered 'Bilateral foot and ankle swelling(left >right).' reason for change: New Information	Lauren Hewitt (b) (4) (b) (4)	14 Apr 2021 17:26:50
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Unilateral leg swelling - version MedDRA\\23.0.	Lauren Hewitt (b) (4) (b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 17:26:50 14 Apr 2021 15:01:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 15:01:00
Data point term sent to Coder	System	14 Apr 2021 15:00:15
User entered 'Left Leg Swelling'	(b) (4), (b) (6) (b) (4)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:21:36
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 14:59:24



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:39
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:41
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:43
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:44
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

**US3482005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:44:17**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:49
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:50
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:52
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24



**US3482005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:44:17**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:54
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:55
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:26:58
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:00
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:02
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:04
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:40
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24



US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:42
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:43
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:45
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:46
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:48
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:27:52
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Source list not applicable. Please verify and update as needed.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:36:00
	(b) (4), (b) (6)	22 Apr 2021 14:35:58
Query 'Source list not applicable. Please verify and update as needed.' answered with 'updated' (Site from CRA).	Mari Hart (b) (4)	22 Apr 2021 14:25:21
User opened query 'Source list not applicable. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:28:22
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:28:25
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24



US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:28:28
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '0' reason for change: New Information	(b) (4)	
	Lauren Hewitt (b) (4)	14 Apr 2021 17:26:50
User entered '1'	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:28:30
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '1' reason for change: New Information	(b) (4)	
	Lauren Hewitt (b) (4)	14 Apr 2021 17:26:50
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:28:32
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:28:34
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:28:36
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:59:24

US3482005

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:44:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 13:28:42
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Participant was contacted today in regards to safety notification from eDiary; subject was seen by PCP for bilateral ankle and foot swelling (left>right). Onset of swelling began at end of day on 4/5/21. Participant was outside gardening and noticed swelling before bedtime. Participant was seen by PCP on 4/8/21 and was told to d/c Glipizide (can cause lower extremity swelling), reduce Amlodipine to 5mg bid po, and begin Hydrochlorothiazide 12.5 mg po qam in order to reduce swelling of lower extremities. Changes to medications were made 4/9/21 and Pt. has not seen change in swelling yet. Per Pt., was not advised to wear compression stockings or elevate legs hs by PCP. Denies any signs/symptoms of DVT. Denies trauma, SOB, or cardiac episodes. Participant works in accounting and sits mostly all day. Notices swelling typically begins mid-day and worse hs. Then, resolves upon awakening and recurs qd. Participant is scheduled to f/u with PCP 5/7/21. Agrees to update with changes. Addendum: Denies pitting in lower extremities.' reason for change: New Information	Lauren Hewitt (b) (4)	14 Apr 2021 17:26:50
User entered 'SUBJECT REPORTED THAT SHE HAS HAD MILD INTERMITTENT SWELLING IN HER LEFT LEG THAT STARTED ON 05APR2021. IT IS NOT PITTING AS PER PATIENT. NO OTHER ASSOCIATED SYMPTOMS. SUBJECT REACHED OUT TO HER MEDICAL PROVIDER AND Was prescribed hydrochlorothiazide and taken off glipizide.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 16:21:36
User entered 'Subject reported that she has had mild intermittent swelling in her left leg that started on 05APR2021. It is not pitting as per patient. No other associated symptoms. Subject reached out to her medical provider and is awaiting further instructions by them but told not to worry.'	(b) (4), (b) (6)	14 Apr 2021 14:59:24

**US3482005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 14:59:24

**US3482005**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 16:21:36
User entered '0'	System	14 Apr 2021 14:59:24



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:44:17

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:07:01
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:08:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:22:51

**Folder: Concomitant Medication and Vaccination (1)**  
**Form: Prior/Concomitant Medication and Vaccination (1)**  
**Generated On: 09 Jun 2021 17:44:17**

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
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)	15 Aug 2020 09:51:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 09:51:13
Data point term sent to Coder	System	14 Aug 2020 16:26:46
User entered 'multivitamin'	(b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:44:17**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 23:17:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:26:05
User entered 'un May 2020'	(b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:44:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:26:05



**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:26:05

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:26:05

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:26:05

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: THIAZOLIDINEDIONES, PRODUCT: PIOGLITAZONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 16:32:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:32:22
Data point term sent to Coder	System	14 Aug 2020 16:31:00
User entered 'Pioglitazone'	(b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:28:51
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 19:58:11
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 19:58:03
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:04:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Diabetes'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '15'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:44:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered 'un Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:30:48

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:30:48

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:30:48

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:30:48

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 16:37:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:37:22
Data point term sent to Coder	System	14 Aug 2020 16:36:07
User entered 'triamterene/hydrochlorothiazide'	(b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:29:44
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 19:58:48
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 19:58:40
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'High blood pressure'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '37.5/25'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 23:17:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:35:54
User entered 'un Jan 2020'	(b) (4), (b) (6)	14 Aug 2020 16:35:54



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:24:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'UN Jan 2021' reason for change: New Information	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:24:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:35:54

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User entered '1'	System	14 Aug 2020 16:35:54

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User entered '1'	System	14 Aug 2020 16:35:54

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:58
User entered '804 (804)'	System	14 Aug 2020 16:35:54

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Sep 2020 14:41:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 14:41:43
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	25 Sep 2020 14:40:24 25 Sep 2020 14:39:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:39:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 16:39:22
Data point term sent to Coder User entered 'Vitamin d3'	System (b) (4), (b) (6)	14 Aug 2020 16:38:14 14 Aug 2020 16:37:30



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:03:34
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. answered with 'Clarified that this is not for diagnosed deficiency' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:39:58
User entered 'Nutritional supplement' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Sep 2020 14:39:35
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:14:18
User entered 'vit d3 deficiency'	(b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:44:17**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '400'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'TU (IU)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:52:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per CDM, IU is one of available options for Dose unit. Please consider changing dose unit from 'Other' to IU and remove value from 'If dose unit is Other, specify' field, otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:29:33
Query 'Per CDM, IU is one of available options for Dose unit. Please consider changing dose unit from 'Other' to IU and remove value from 'If dose unit is Other, specify' field, otherwise explain.' answered with 'dose unit has been changed to IU.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:52:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:52:00
User opened query 'Per CDM, IU is one of available options for Dose unit. Please consider changing dose unit from 'Other' to IU and remove value from 'If dose unit is Other, specify' field, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:05:21
User entered 'IU'	(b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:30



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered 'un Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:44:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:30

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:37:30

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:37:30



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:37:30

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BAYER ASPIRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 17:34:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:34:28
Data point term sent to Coder	System	14 Aug 2020 16:42:31
User entered 'Bayer Aspirin'	(b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '325'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:44:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 23:17:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:41:43
User entered 'un UNK 2016'	(b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:43



**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:41:43

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:41:43

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:41:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, PRODUCT: BIMATOPROST;BRIMONIDINE;TIMOLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Oct 2020 05:20:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 05:20:39
Data point term sent to Coder	System	29 Sep 2020 13:28:39
Data point term sent to Coder	System	18 Sep 2020 15:33:02
Data point term sent to Coder	System	16 Sep 2020 19:42:21
Data point term sent to Coder	System	10 Sep 2020 13:58:26
Coding entries removed.	(b) (4), (b) (6)	10 Sep 2020 13:57:49
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, PRODUCT: BIMATOPROST;BRIMONIDINE;TIMOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 10:14:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 10:14:46
Data point term sent to Coder	System	03 Sep 2020 21:03:22
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	03 Sep 2020 21:03:01
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'Added requested info' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 21:03:01
Data point term sent to Coder	System	03 Sep 2020 18:21:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'LUMIGAN COMBIGAN TIMOLOL (brimonidine/timolol) (bimatoprost)'	(b) (4), (b) (6)	03 Sep 2020 18:20:51
reason for change: Per Query Resolution		
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	17 Aug 2020 10:28:05
Data point term sent to Coder	System	14 Aug 2020 16:45:37
User entered 'Lumigan	(b) (4), (b) (6)	14 Aug 2020 16:45:00
Combigan		
Timolol'		

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:28:30
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:12:30
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 20:12:22
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:05:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Please update the indication to reflect the location if Bilateral, Left, or Right. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:28:24
Query 'Per DM CLR: Please update the indication to reflect the location if Bilateral, Left, or Right. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:28:16
User entered 'BILATERAL GLAUCOMA' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Sep 2020 13:28:11
User opened query 'Per DM CLR: Please update the indication to reflect the location if Bilateral, Left, or Right. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:05:30
User entered 'Glaucoma'	(b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'unk'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:00



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'unk'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	03 Sep 2020 18:20:51
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	14 Aug 2020 16:45:00
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6) [REDACTED]	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:20:51
User entered 'takes unknown dose of eye gtts unk frequency'	(b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per CDM: Thank you for the update and apologies for the confusion. Intraocular is an available option in the drop down for route of administration. Please consider updating the route of administration to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 04:11:22
Query 'Per CDM: Thank you for the update and apologies for the confusion. Intraocular is an available option in the drop down for route of administration. Please consider updating the route of administration to the available equivalent rather than Other. Thank you.' answered with 'Updated to intraocular' (Site from DM).		18 Sep 2020 15:32:52
User entered 'Intraocular (INTRAOCULAR)' reason for change: Per Query Resolution		18 Sep 2020 15:32:31
User opened query 'Per CDM: Thank you for the update and apologies for the confusion. Intraocular is an available option in the drop down for route of administration. Please consider updating the route of administration to the available equivalent rather than Other. Thank you.' (Site from DM).		17 Sep 2020 15:36:02
User closed query 'Per CDM: Thank you for your response. Since DROP is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Topical. Thank you.' (Site from DM).		17 Sep 2020 15:03:09
Query 'Per CDM: Thank you for your response. Since DROP is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Topical. Thank you.' answered with 'I don't have DROP as an option in the drop down menu so I updated this as Other instead' (Site from DM).		16 Sep 2020 19:42:17
User entered 'Other (OTHER)' reason for change: Per Query Resolution		16 Sep 2020 19:41:48
User opened query 'Per CDM: Thank you for your response. Since DROP is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Topical. Thank you.' (Site from DM).		11 Sep 2020 18:46:56

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: 'Route of administration' is 'Other' and 'If route of administration is Other, specify' is entered as 'EYE'. Please confirm if any other suitable predefined option is available under the data field 'Route of administration' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:46:56
Query 'Per CDM: 'Route of administration' is 'Other' and 'If route of administration is Other, specify' is entered as 'EYE'. Please confirm if any other suitable predefined option is available under the data field 'Route of administration' for this medication and update as required. Otherwise please provide explanation.' answered with 'route of administration changed to topical. this is an eyedrop.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:02:21
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:57:49
User opened query 'Per CDM: 'Route of administration' is 'Other' and 'If route of administration is Other, specify' is entered as 'EYE'. Please confirm if any other suitable predefined option is available under the data field 'Route of administration' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:50:46
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty; reason for change Per Query Resolution	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:32:31
User entered 'Drop' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Sep 2020 19:41:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:57:49
User entered 'eye'	(b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered empty; reason for change Per Query Resolution	System	03 Sep 2020 18:20:51
	(b) (4), (b) (6)	03 Sep 2020 18:20:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 16:45:00
User entered 'un UNK unkn' (non-conformant).	(b) (4), (b) (6)	14 Aug 2020 16:45:00



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:00

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:45:00

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:45:00

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:45:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 09:40:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 09:40:14
Data point term sent to Coder	System	14 Aug 2020 16:46:39
User entered 'omeprazole'	(b) (4), (b) (6)	14 Aug 2020 16:46:19



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 20:29:05
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Updated' (Site from DM).		24 Sep 2020 20:13:06
User entered 'No (N)' reason for change: Per Query Resolution		24 Sep 2020 20:12:59
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).		24 Sep 2020 05:10:19
User entered 'Yes (Y)'		14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'ulcer'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '20'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:44:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:46:19

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:46:19

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:46:19



**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:46:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 16:48:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:48:24
Data point term sent to Coder	System	14 Aug 2020 16:47:44
User entered 'glipizide'	(b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:29:15
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:13:30
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 20:13:24
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'diabetes'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '20'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 16:22:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:22:10
User entered '08 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 16:22:10
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:38



**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:47:38

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:47:38

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:47:38

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 16:50:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:50:22
Data point term sent to Coder	System	14 Aug 2020 16:49:47
User entered 'losartan'	(b) (4), (b) (6) [REDACTED]	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 19:03:10
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:13:56
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 20:13:50
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:07:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'high blood pressure'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '10'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:02



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:44:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 16:49:32
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 16:49:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:50:36
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:49:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 16:49:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:49:32
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:49:02
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:49:02



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4) System	14 Aug 2020 16:50:36
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	14 Aug 2020 16:49:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:02

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:49:02

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:49:02

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:49:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 14:07:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 14:07:54
Data point term sent to Coder	System	01 Oct 2020 14:07:23
User entered 'Biotin'	(b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 23:20:52
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Not prophylaxis as there is not a specific disease biotin prevents' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 21:12:02
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 03:42:57
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 03:42:50
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 03:42:46
User entered 'Nutritional supplement'	(b) (4), (b) (6)	01 Oct 2020 14:07:22



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:41:01
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Exact dosage unknown' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 21:12:19
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 03:43:10
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:44:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:44:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:44:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:44:17**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:44:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:07:22

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 14:07:22

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 14:07:22

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 14:07:22

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 16:55:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:55:22
Data point term sent to Coder	System	14 Aug 2020 16:54:06
User entered 'atrovastatin'	(b) (4), (b) (6) [REDACTED]	14 Aug 2020 16:54:02
	[REDACTED]	



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:29:35
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:14:37
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 20:14:30
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:09:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'high cholesterol'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '80'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:54:02

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:54:02

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:54:02



**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:54:02

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:11:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:11:42
Data point term sent to Coder	System	10 Sep 2020 14:10:48
Coding entries removed.	(b) (4), (b) (6)	10 Sep 2020 14:10:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 23:36:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 23:36:28
Data point term sent to Coder	System	14 Aug 2020 16:56:12
User entered 'fluticasone'	(b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '50'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 04:08:15
Query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 15:38:28
User entered 'ug (ug)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Sep 2020 15:38:18
User opened query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:36:10
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:38:18
User entered 'mcg'	(b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per CDM: As needed is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 04:09:36
Query 'Per CDM: As needed is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 15:38:32
User entered 'as needed (PRN)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Sep 2020 15:38:18
User opened query 'Per CDM: As needed is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:36:43
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:55:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 16:55:48
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:55:48
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:55:14
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:55:14



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:38:18
User entered 'prn'	(b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:10:37
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per CDM, Nasal is one of available options for Route of administration. Please consider changing Route of administration from 'Other' to Nasal and remove value from 'If route of administration is Other, specify' field, otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:35:50
Query 'Per CDM, Nasal is one of available options for Route of administration. Please consider changing Route of administration from 'Other' to Nasal and remove value from 'If route of administration is Other, specify' field, otherwise explain.' answered with 'route updated to nasal' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:10:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:10:37
User opened query 'Per CDM, Nasal is one of available options for Route of administration. Please consider changing Route of administration from 'Other' to Nasal and remove value from 'If route of administration is Other, specify' field, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:08:56
User entered 'nasal'	(b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:44:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:55:14



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:55:14

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:55:14

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:55:14

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:10:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE HYDROCHLORIDE, PRODUCTSYNONYM: ZICAM [OXYMETAZOLINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:15:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:15:33
Data point term sent to Coder	System	10 Sep 2020 14:13:51
Coding entries removed.	(b) (4), (b) (6)	10 Sep 2020 14:13:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE HYDROCHLORIDE, PRODUCTSYNONYM: ZICAM [OXYMETAZOLINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 10:18:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 10:18:51
Data point term sent to Coder	System	03 Sep 2020 21:04:24
User closed query 'For coding purposes, references indicate different formulations for ZYCAM. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	03 Sep 2020 21:03:44
Query 'For coding purposes, references indicate different formulations for ZYCAM. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'Added requested info' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 21:03:44

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	03 Sep 2020 18:24:07
User entered 'ZICAM (oxymetazoline nasal)' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Sep 2020 18:23:08
User opened query 'For coding purposes, references indicate different formulations for ZYCAM. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4)	16 Aug 2020 12:25:07
Data point term sent to Coder	System	14 Aug 2020 16:57:14
User entered 'zicam'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:31
User entered 'unknown'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:32
User entered 'unk'	(b) (4), (b) (6)	14 Aug 2020 16:56:44



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:34
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:41
User entered 'unknown'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:10:42
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:13:20
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	14 Aug 2020 16:57:15
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:57:15
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:57:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 16:57:02
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	14 Aug 2020 16:57:02
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:57:02
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 16:56:44
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:45
User closed query 'Per CDM, As needed is one of available options for Frequency. Please consider changing Frequency from 'Other' to 'As needed' and remove value from 'If frequency is Other, specify' field, otherwise explain.	(b) (4), (b) (6)	11 Sep 2020 17:36:09
' (Site from DM).		
Query 'Per CDM, As needed is one of available options for Frequency. Please consider changing Frequency from 'Other' to 'As needed' and remove value from 'If frequency is Other, specify' field, otherwise explain.	(b) (4), (b) (6)	10 Sep 2020 14:13:47
' answered with 'updated frequency to as needed' (Site from DM).		
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:13:20
User opened query 'Per CDM, As needed is one of available options for Frequency. Please consider changing Frequency from 'Other' to 'As needed' and remove value from 'If frequency is Other, specify' field, otherwise explain.	(b) (4), (b) (6)	09 Sep 2020 12:10:48
' (Site from DM).		
User entered 'as needed'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:46
User entered 'Nasal (NASAL)' reason for change:	(b) (4), (b) (6)	10 Sep 2020 14:13:20
Data Entry Error		
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:48
User closed query 'Per CDM, Nasal is one of available options for Route of administration. Please consider changing Route of administration from 'Other' to Nasal and remove value from 'If route of administration is Other, specify' field, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 17:36:11
Query 'Per CDM, Nasal is one of available options for Route of administration. Please consider changing Route of administration from 'Other' to Nasal and remove value from 'If route of administration is Other, specify' field, otherwise explain.' answered with 'updated route to nasal' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:13:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:13:20
User opened query 'Per CDM, Nasal is one of available options for Route of administration. Please consider changing Route of administration from 'Other' to Nasal and remove value from 'If route of administration is Other, specify' field, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:09:27
User entered 'nasal'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Query 'Per source, start date is UNK. Please confirm and update.' canceled (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:10:55
	(b) (4), (b) (6)	04 Feb 2021 22:10:49
User opened query 'Per source, start date is UNK. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 22:10:23
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:53
User entered 'I'	(b) (4), (b) (6)	14 Aug 2020 16:56:44



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:10:59
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 16:56:44

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:56:44

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:56:44

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:56:44

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 17:06:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 17:06:21
Data point term sent to Coder	System	05 Nov 2020 17:05:13
User entered 'Influenza vaccine'	(b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'preventative'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0.5'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'UN Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'UN Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:18

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User entered empty.	System	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User entered empty.	System	05 Nov 2020 17:04:18

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:44:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:07:05
User entered empty.	System	05 Nov 2020 17:04:18



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:16:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE HYDROCHLORIDE, PRODUCTSYNONYM: ZICAM [OXYMETAZOLINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:39:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:39:52
Data point term sent to Coder	System	08 Jan 2021 21:53:25
Data point term sent to Coder	System	08 Jan 2021 21:52:24
User entered 'ZICAM (OXYMETAZOLINE NASAL)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:16:50
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:16:52
User entered 'Runny nose' reason for change: Data Entry Error	Joy Winters (b) (4)	08 Jan 2021 21:52:53
User entered 'Flu-like illness'	(b) (4) Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:16:54
User entered 'UNK'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:16:55
User entered 'Other (OTHER)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:16:57
User entered 'UNK'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:16:58
User entered 'as needed (PRN)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:17:00
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:17:02
User entered 'Nasal (NASAL)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:17:06
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:17:10
User entered '27 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:17:08
User entered '0'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:17:40
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:17:42
User entered '30 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:17:44
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:51:31

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User entered empty.	System	08 Jan 2021 21:51:31



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User entered empty.	System	08 Jan 2021 21:51:31

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:45
User entered empty.	System	08 Jan 2021 21:51:31

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM; MANGANESE;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC, PRODUCTSYNONYM: AIRBORNE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 17:23:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 17:23:55
Data point term sent to Coder	System	11 Feb 2021 17:23:27
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 17:23:12
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 18:18:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM; MANGANESE;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC, PRODUCTSYNONYM: AIRBORNE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 22:41:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 22:41:23
Data point term sent to Coder	System	29 Jan 2021 22:40:09
Coding entries removed.	(b) (4), (b) (6)	29 Jan 2021 22:40:00

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM; MANGANESE;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC, PRODUCTSYNONYM: AIRBORNE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 21:56:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 21:56:55
Data point term sent to Coder	System	08 Jan 2021 21:55:28
User entered 'Airborne'	Joy Winters (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:55:01
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:23:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 17:23:12
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 18:18:17
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 01:45:12
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'This medication is taken prophylactically. This indication is to boost immune support but is not indicative of an underlying health condition. Please resolve. ' (Site from DM).	Lauren Hewitt (b) (4) (b) (4)	02 Apr 2021 16:17:48
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:57:00
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:55:04
User closed query 'Per source, this medication was given for immune support. Please confirm and reconcile .' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:54:57
Query 'Per source, this medication was given for immune support. Please confirm and reconcile .' answered with 'prophylaxis and indication updated' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:23:33
User entered 'immune support' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 17:23:12
User opened query 'Per source, this medication was given for immune support. Please confirm and reconcile .' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 18:19:10
User entered 'UPPER RESPIRATORY SYMPTOMS' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Jan 2021 22:40:00

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:44:17**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Immune support'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:15
User entered 'UNK'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:27
User entered 'Other (OTHER)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:29
User entered 'UNK'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:31
User entered 'as needed (PRN)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:32
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:34
User entered 'Oral (ORAL)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:36
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:37
User entered '27 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:39
User entered '0'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:41
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:42
User entered '27 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:19:43
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:55:19

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User entered empty.	System	08 Jan 2021 21:55:19

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User entered empty.	System	08 Jan 2021 21:55:19

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:08:02
User entered empty.	System	08 Jan 2021 21:55:19

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEP HRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU DAYTIME SEVERE COLD & COUGH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:33:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:33:52
Data point term sent to Coder	System	02 Apr 2021 16:35:20
Coding entries removed.	(b) (4), (b) (6)	02 Apr 2021 16:35:19
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEP HRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU MULTI SYMPTOM SEVERE COLD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 13:43:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 13:43:37
Data point term sent to Coder	System	11 Feb 2021 17:25:30
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 18:20:04
Data point term sent to Coder	System	29 Jan 2021 22:41:10
Data point term sent to Coder	System	28 Jan 2021 20:07:12
User closed query 'For coding purposes, the reported trade name can be referenced with different formulations in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	System	28 Jan 2021 20:06:48

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'For coding purposes, the reported trade name can be referenced with different formulations in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' answered with 'active ingredients added' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 20:06:48
User entered 'THERAFLU(Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 20:06:35
User opened query 'For coding purposes, the reported trade name can be referenced with different formulations in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	09 Jan 2021 00:32:45
Data point term sent to Coder	System	08 Jan 2021 21:58:29
User entered 'Theraflu'	Joy Winters (b) (4)	08 Jan 2021 21:57:52
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:22:28
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:16:51
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 16:35:19
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 16:35:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 16:35:19
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:55:17
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:24:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 17:24:56
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 18:20:05
User entered 'No (N)'	Joy Winters (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:22:31
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:16:51
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 01:51:16
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 16:35:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Apr 2021 16:35:19
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 16:35:19
User entered 'Covid-19' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Apr 2021 16:35:19
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:57:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:55:20
User closed query 'Per source, this medication was given for immune support. Please confirm and reconcile or make corrections to the source.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:55:15
Query 'Per source, this medication was given for immune support. Please confirm and reconcile or make corrections to the source.' answered with 'prophylaxis and indication updated' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:25:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User entered 'immune support' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 17:24:56
User opened query 'Per source, this medication was given for immune support. Please confirm and reconcile or make corrections to the source.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 18:20:48
User entered 'UPPER RESPIRATORY SYMPTOMS' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Jan 2021 22:40:22
User entered 'Immune support'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:20:54
User entered 'UNK'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:20:56
User entered 'Other (OTHER)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:20:57
User entered 'UNK'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:20:59
User entered 'as needed (PRN)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:21:00
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:21:02
User entered 'Oral (ORAL)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:21:07
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:21:09
User entered '27 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:21:12
User entered '0'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:21:15
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:21:16
User entered '30 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:21:19
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 21:57:52

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User entered empty.	System	08 Jan 2021 21:57:52



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User entered empty.	System	08 Jan 2021 21:57:52

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:57:18
User entered empty.	System	08 Jan 2021 21:57:52

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE, PRODUCTSYNONYM: HYDROMET [HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:00:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:00:48
Data point term sent to Coder	System	08 Jan 2021 22:00:29
User entered 'Hydromet'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:15
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:17
User entered 'Runny nose'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:19
User entered '2.5'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:20
User entered 'mL (mL)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:22
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:24
User entered 'once daily (QD)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:25
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:27
User entered 'Oral (ORAL)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:29
User entered empty.	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:30
User entered '27 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:32
User entered '0'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:34
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:37
User entered '30 Dec 2020'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:24:39
User entered 'No (N)'	Joy Winters (b) (4) (b) (4)	08 Jan 2021 22:00:09

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User entered '1'	System	08 Jan 2021 22:00:09

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User entered '1'	System	08 Jan 2021 22:00:09

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:43:46
User entered '804 (804)'	System	08 Jan 2021 22:00:09

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HIGH BLOOD PRESSURE; update Con Med indication or provide clarification. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 09:21:31
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HIGH BLOOD PRESSURE; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 09:20:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 19:28:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 19:28:48
Data point term sent to Coder	System	06 Feb 2021 19:27:30
User entered 'Amlodipine'	(b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'High blood pressure'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '10'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'UN Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 19:26:55

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Feb 2021 19:26:55

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Feb 2021 19:26:55

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Feb 2021 19:26:55

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 13 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 19:07:06
Query 'Per DM CLR: this Con Med was added/ had dose increased on 13 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'This con med change was not due not due to worsening of MH. Pt was switched to this medication per PCP since pt was taking metformin for years ' (Site from DM).	Lauren Hewitt (b) (4)	08 Apr 2021 13:25:08
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 13 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:58:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 15:51:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 15:51:46
Data point term sent to Coder	System	12 Mar 2021 15:51:04
User entered 'Ozempic'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11

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US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered 'No (N)'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered 'Diabetes'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered '0.5'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered 'mg (mg)'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:44:17**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered empty.	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User closed query 'Per CDM: Every week is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 08:17:00
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	23 Mar 2021 15:01:03
Query 'Per CDM: Every week is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'updated' (Site from DM).	Mari Hart (b) (4) (b) (4)	23 Mar 2021 15:00:23
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	23 Mar 2021 14:59:47
User entered 'every week (QS)' reason for change: Per Query Resolution	Mari Hart (b) (4) (b) (4)	23 Mar 2021 14:59:47
User opened query 'Per CDM: Every week is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 19:11:41
User entered 'other (OTHER)'	Lauren Hewitt (b) (4) (b) (4)	12 Mar 2021 15:50:11

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty; reason for change Per Query Resolution	(b) (4) Mari Hart (b) (4)	23 Mar 2021 15:01:03
User entered 'q weekly'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:44:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered empty.	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered '13 Jan 2021'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:44:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered '0'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:44:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered 'Yes (Y)'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered empty.	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
	(b) (4)	
User entered 'No (N)'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:11
	(b) (4)	

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 14:59:47
User entered empty.	System	12 Mar 2021 15:50:11

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 14:59:47
User entered empty.	System	12 Mar 2021 15:50:11

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	23 Mar 2021 14:59:47
User entered empty.	System	12 Mar 2021 15:50:11



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Mar 2021 15:51:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 15:51:45
Data point term sent to Coder	System	12 Mar 2021 15:51:04
User entered 'Metformin'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Diabetes'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '500'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'mg (mg)'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'twice daily (BID)'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'Oral (ORAL)'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered empty.	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'un UNK 2016'	(b) (4) Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '0'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '13 Jan 2021'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	Lauren Hewitt (b) (4)	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User entered '2'	System	12 Mar 2021 15:50:50



**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User entered '1'	System	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:44:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:17:06
User entered '804 (804)'	System	12 Mar 2021 15:50:50

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 16:24:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 16:24:57
Data point term sent to Coder	System	14 Apr 2021 16:24:43
User entered 'Hydrochlorothiazide'	(b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'leg swelling'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '25'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:44:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:07:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:23:43

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 16:23:43

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 16:23:43

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Apr 2021 16:23:43

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 21:05:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 21:05:06
Data point term sent to Coder	System	23 Apr 2021 21:04:29
User entered 'Amlodipine'	Michelle Wiles (b) (4) (b) (4)	23 Apr 2021 21:03:58

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:44:17**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'Hypertension'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered '5'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	



US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'mg (mg)'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:44:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'twice daily (BID)'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:44:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered '08 Apr 2021'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered '0'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	



US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:44:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:44:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:44:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:38
	(b) (4)	
User entered 'No (N)'	Michelle Wiles (b) (4)	23 Apr 2021 21:03:58
	(b) (4)	

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:44:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 21:03:58

US3482005

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 21:03:58

**US3482005**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:44:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 21:03:58

US3482005

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 17:44:17**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:36:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:50:11

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'USA-US106-2021-MRNA-1273-P301000006'	System	21 Jan 2021 18:29:42



**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 20:57:43
Signature has been broken.	System	30 Mar 2021 20:57:43
User entered 'Nadine'	System	30 Mar 2021 20:57:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'Easton'	System	21 Jan 2021 18:29:42



US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 20:57:43
Signature has been broken.	System	30 Mar 2021 20:57:43
User entered 'Rouphael'	System	30 Mar 2021 20:57:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'Beshears'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '500 Irvin Court'	(b) (4) System	30 Mar 2021 20:57:43

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Decatur'	(b) (4) System	30 Mar 2021 20:57:43

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'GA'	(b) (4) System	30 Mar 2021 20:57:43

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '30030'	(b) (4) System	30 Mar 2021 20:57:43

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:53
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:07:04
User entered 'US'	System	21 Jan 2021 18:30:29

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Mar 2021 20:57:43
User entered '2'	System	12 Feb 2021 19:27:02
User entered '1'	System	21 Jan 2021 18:30:29

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered		
'USA-US106-2021-MRNA-1273-P301000006'	System	21 Jan 2021 18:29:42



**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 20:57:43
Signature has been broken.	System	30 Mar 2021 20:57:43
User entered 'Nadine'	System	30 Mar 2021 20:57:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'Easton'	System	21 Jan 2021 18:29:42



US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 20:57:43
Signature has been broken.	System	30 Mar 2021 20:57:43
User entered 'Rouphael'	System	30 Mar 2021 20:57:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'Beshears'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '500 Irvin Court'	(b) (4) System	30 Mar 2021 20:57:43

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Decatur'	(b) (4) System	30 Mar 2021 20:57:43

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'GA'	(b) (4) System	30 Mar 2021 20:57:43

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '30030'	(b) (4) System	30 Mar 2021 20:57:43

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:53
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:07:04
User entered 'US'	System	21 Jan 2021 18:30:29

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Mar 2021 20:57:43
User entered '2'	System	12 Feb 2021 19:27:02
User entered '1'	System	21 Jan 2021 18:30:29

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:44:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
User entered '21/Jan/2021 18:30'	System	21 Jan 2021 18:30:29



US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:44:17

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:53
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:07:04
User entered 'I'	(b) (4), (b) (6)	21 Jan 2021 18:30:29

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered		
'USA-US106-2021-MRNA-1273-P301000006'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42



US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 20:57:43
Signature has been broken.	System	30 Mar 2021 20:57:43
User entered 'Nadine'	System	30 Mar 2021 20:57:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'Easton'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 20:57:43
Signature has been broken.	System	30 Mar 2021 20:57:43
User entered 'Rouphael'	System	30 Mar 2021 20:57:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'Beshears'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '500 Irvin Court'	(b) (4) System	30 Mar 2021 20:57:43

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Decatur'	(b) (4) System	30 Mar 2021 20:57:43

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'GA'	(b) (4) System	30 Mar 2021 20:57:43

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '30030'	(b) (4) System	30 Mar 2021 20:57:43

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:53
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:07:04
User entered 'US'	System	21 Jan 2021 18:30:29



**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Mar 2021 20:57:43
User entered '2'	System	12 Feb 2021 19:27:02
User entered '1'	System	21 Jan 2021 18:30:29

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:44:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered '12/Feb/2021 14:27'	(b) (4) System	12 Feb 2021 19:27:02

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:44:17

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 20:57:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:27:02

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered		
'USA-US106-2021-MRNA-1273-P301000006'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42



**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'No (N)'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 20:57:43
Signature has been broken.	System	30 Mar 2021 20:57:43
User entered 'Nadine'	System	30 Mar 2021 20:57:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'Easton'	System	21 Jan 2021 18:29:42

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	30 Mar 2021 20:57:43
Signature has been broken.	System	30 Mar 2021 20:57:43
User entered 'Rouphael'	System	30 Mar 2021 20:57:43
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 22:07:04
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:30:22
User entered 'Beshears'	System	21 Jan 2021 18:29:42

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '500 Irvin Court'	(b) (4) System	30 Mar 2021 20:57:43

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'Decatur'	(b) (4) System	30 Mar 2021 20:57:43

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'GA'	(b) (4) System	30 Mar 2021 20:57:43



**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '30030'	(b) (4) System	30 Mar 2021 20:57:43

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:44:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:17:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:26:53
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:07:04
User entered 'US'	System	21 Jan 2021 18:30:29

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:44:17**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Mar 2021 20:57:43
User entered '2'	System	12 Feb 2021 19:27:02
User entered '1'	System	21 Jan 2021 18:30:29

**US3482005**

**Folder: SAE USA-US106-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:44:17**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered '30/Mar/2021 16:57'	(b) (4) System	30 Mar 2021 20:57:43

US3482005

Folder: SAE USA-US106-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:44:17

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:20:57
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 21:57:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:57:43