

US3472096 (Prod: Penn Prevention - (CRS))

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:46:48

All time stamps listed in this document are displayed in GMT

US3472096

**Form: Participant Creation**

**Data signed:** (b) (4) 02 May 2021 19:11:26

**Generated On: 11 Aug 2021 22:46:48**

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[Participant ID](#)

US3472096

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

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US3472096

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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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	SCRN

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US3472096

Folder: Screening

Form: Demographics

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	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

US3472096

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Date of Informed Consent (*dd MMM yyyy*) 7 OCT 2020

Month and Year of Informed Consent (derived) OCT 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3472096

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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Did the participant meet all eligibility criteria?

Yes

No

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US3472096

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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Were any significant conditions reported?

Yes

No

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US3472096

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	BORDERLINE PERSONALITY DISORDER
Start date (dd MMM yyyy)	UN JAN 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3472096

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	HERNIATED DISC, L5-S1
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	SEP 2005
Stop Year (derived)	2005

US3472096

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3472096

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3472096

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	11:27 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:27
Height ( <i>xxx.x</i> )	190.5 cm
Weight ( <i>xxx.x</i> )	126 kg
BMI ( <i>xxx.x</i> )	34.72007 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)	_____

US3472096

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

7 OCT 2020

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

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US3472096

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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**Occupational Risk**

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**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** IT

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**Location and Living Circumstances Risk (check all that apply)**

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**No Risk Identified** False

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

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US3472096

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 7 OCT 2020

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

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Folder OID VISIT1

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US3472096

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

What was the date of randomization? (dd MMM yyyy) 07 OCT 2020

What was the participant's randomization number? 116343

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

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

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

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

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

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

Liver Disease Yes  No

Human Immunodeficiency Virus (HIV) infection Yes  No

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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Height	ND - Not Done
Weight	ND - Not Done

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US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	11:27 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:27
Temperature ( <i>xxx.x</i> )	37.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	75 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	93 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:23 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 13:23
Temperature ( <i>xxx.x</i> )	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	69 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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Was the physical examination performed?

Yes

No

---

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

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

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US3472096

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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) 7 OCT 2020

What was the treatment time? (00:00-23:59) 13:01 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 13:01

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

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 7 OCT 2020

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Collection time (*00:00-23:59*) 11:55 (24 HR)

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Collection date and time (derived) 7 OCT 2020 11:55

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US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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Collection date ( <i>dd MMM yyyy</i> )			7 OCT 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:47	7 OCT 2020 11:47
Nasopharyngeal Swab 2	No		

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US3472096

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.8 °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 07 OCT 2020 13:26

PC Open Date & Time 07 OCT 2020 13:21

PC Close Date & Time 07 OCT 2020 15:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp 07 OCT 2020 18:03  
PC Open Date & Time 07 OCT 2020 16:46  
PC Close Date & Time 08 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 OCT 2020 12:35
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 OCT 2020 16:29
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 OCT 2020 20:43
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**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):

To **TREAT** pain or fever that has already occurred True

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

PC Time Stamp 11 OCT 2020 19:06

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**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 97.3 °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):

To **TREAT** pain or fever that has already occurred True

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

PC Time Stamp 12 OCT 2020 12:45

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.2 °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):

To **TREAT** pain or fever that has already occurred True

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

PC Time Stamp 13 OCT 2020 20:48

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 8

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.3 °F

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

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

To **TREAT** pain or fever that has already occurred True

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

PC Time Stamp 14 OCT 2020 12:37

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 9

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):

To **TREAT** pain or fever that has already occurred True

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

PC Time Stamp 15 OCT 2020 20:06

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.4 °F

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

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

PC Time Stamp 16 OCT 2020 14:29

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**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	07 OCT 2020 13:26
PC Open Date & Time	07 OCT 2020 13:21
PC Close Date & Time	07 OCT 2020 15:51

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**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

07 OCT 2020 17:52

PC Open Date & Time

07 OCT 2020 16:46

PC Close Date & Time

08 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	08 OCT 2020 12:36
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 3

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

Please select one response below

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

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

- Yes
- No

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 OCT 2020 12:03
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 4

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	10 OCT 2020 20:42
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 5

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

Please select one response below

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

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

- Yes
- No

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	11 OCT 2020 19:05
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

12 OCT 2020 12:46

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

13 OCT 2020 20:48

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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

No

Yes

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PC Time stamp	07 OCT 2020 13:27
PC Open Date & Time	07 OCT 2020 13:21
PC Close Date & Time	07 OCT 2020 15:51

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US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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

No

Yes

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PC Time stamp	07 OCT 2020 17:53
PC Open Date & Time	07 OCT 2020 16:46
PC Close Date & Time	08 OCT 2020 11:59

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US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

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	Yes <input type="checkbox"/>
PC Time stamp	08 OCT 2020 12:36
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

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US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

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	Yes <input type="checkbox"/>
PC Time stamp	09 OCT 2020 12:02
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

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US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

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	Yes <input type="checkbox"/>
PC Time stamp	10 OCT 2020 20:42
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

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US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

---

	Yes <input type="checkbox"/>
PC Time stamp	11 OCT 2020 17:47
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

---

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

---

	Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 12:46
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

---

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

---

	Yes <input type="checkbox"/>
PC Time stamp	13 OCT 2020 20:49
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

---

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:46:48

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 OCT 2020 12:37
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:46:48

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 20:06
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:46:48

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 14:28
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3472096

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3472096

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3472096

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 04 NOV 2020

---

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

---

Folder OID VISIT2

---

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 16:02:26

Generated On: 11 Aug 2021 22:46:48

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	04 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	11:02 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 11:02
Temperature ( <i>xxx.x</i> )	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	69 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	91 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 16:02:26

Generated On: 11 Aug 2021 22:46:48

Timepoint Pre-Dose   
Post-Dose

Were vital signs assessed? Yes   
No

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

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

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

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

Route of measurement Oral   
Axillary   
Other

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

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

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

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

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

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

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

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

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

US3472096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

04 NOV 2020

---

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

---

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

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

PARTICIPANT NEEDED TO LEAVE FOR ANOTHER APPOINTMENT.

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

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

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

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

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

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

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

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 04 NOV 2020

---

Collection time (*00:00-23:59*) 11:09 (24 HR)

---

Collection date and time (derived) 04 NOV 2020 11:09

---

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Collection date ( <i>dd MMM yyyy</i> )			04 NOV 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:06	04 NOV 2020 11:06
Nasopharyngeal Swab 2	No		

---

US3472096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

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 PARTICIPANT ON ILLNESS TRACK

---

*If Contact Not Made, please provide Comments*

---

US3472096

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

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 PARTICIPANT ON ILLNESS TRACK

---

*If Contact Not Made, please provide Comments*

---

US3472096

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

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 PARTICIPANT ON ILLNESS TRACK

---

*If Contact Not Made, please provide Comments*

---

US3472096

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:02:26

Generated On: 11 Aug 2021 22:46:48

---

Was this visit performed? Yes   
No

---

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

---

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

---

Folder OID VISIT3

---

US3472096

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

---

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.*

---

US3472096

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Was the sample collected? Yes   
No

Collection date (*dd MMM yyyy*) \_\_\_\_\_

Collection time (*00:00-23:59*) \_\_\_\_\_

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

US3472096

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:26

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

<b>TIMEPOINT</b>	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 12:51:16
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 16:16:52
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 75

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	18 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 82

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

No

Yes

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 12:07:33

Patient Cloud Open Date & Time 25 DEC 2020 00:01

Patient Cloud Close Date & Time 29 DEC 2020 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 89

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

No

Yes

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

No

Yes

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

Date and time of submission 04 JAN 2021 13:29:31

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

Patient Cloud Close Date & Time 05 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 13:34:14
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <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	15 JAN 2021 08:47:02
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 07:18:53
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 07:51:51
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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	05 FEB 2021 22:05:46
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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 12 FEB 2021 07:36:59

Patient Cloud Open Date & Time 12 FEB 2021 00:01

Patient Cloud Close Date & Time 16 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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	19 FEB 2021 07:03:08
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 145

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

No

Yes

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

No

Yes

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

Date and time of submission 02 MAR 2021 09:53:16

Patient Cloud Open Date & Time 26 FEB 2021 00:01

Patient Cloud Close Date & Time 02 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 07:44:47
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 07:07:20
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	19 MAR 2021 12:21:35
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 MAR 2021 12:07:30
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 APR 2021 10:22:49
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 187

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

No

Yes

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

No

Yes

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

Date and time of submission 13 APR 2021 09:37:14

Patient Cloud Open Date & Time 09 APR 2021 00:01

Patient Cloud Close Date & Time 13 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission 16 APR 2021 07:31:07

Patient Cloud Open Date & Time 16 APR 2021 00:01

Patient Cloud Close Date & Time 20 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 07:22:24
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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 30 APR 2021 06:48:04

Patient Cloud Open Date & Time 30 APR 2021 00:01

Patient Cloud Close Date & Time 04 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 215

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

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

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

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

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

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 222

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	14 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 MAY 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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°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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 236

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 243

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 264

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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°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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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09 JUL 2021 00:01

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13 JUL 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

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20 JUL 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

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

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

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

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Date and time of submission

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23 JUL 2021 00:01

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27 JUL 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

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

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**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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30 JUL 2021 00:01

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03 AUG 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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06 AUG 2021 00:01

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10 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

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13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 320

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 20 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 24 AUG 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 334

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3472096

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Date and time of submission

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03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 341

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3472096

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

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Date and time of submission

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 SEP 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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

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[Patient Cloud Close Date & Time](#) 05 OCT 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	08 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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°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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	26 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 07 DEC 2021 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	17 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	31 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 460

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

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

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

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

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

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

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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07 JAN 2022 00:01

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11 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

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18 JAN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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21 JAN 2022 00:01

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25 JAN 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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28 JAN 2022 00:01

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01 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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04 FEB 2022 00:01

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08 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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11 FEB 2022 00:01

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15 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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18 FEB 2022 00:01

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22 FEB 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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25 FEB 2022 00:01

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01 MAR 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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04 MAR 2022 00:01

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08 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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11 MAR 2022 00:01

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15 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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18 MAR 2022 00:01

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22 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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25 MAR 2022 00:01

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29 MAR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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°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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	15 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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°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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	22 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 APR 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	20 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAY 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 600

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 621

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

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21 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2022 00:01
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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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09 AUG 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	19 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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30 AUG 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3472096**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 SEP 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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09 SEP 2022 00:01

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13 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

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20 SEP 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#) 11 OCT 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 740

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

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

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

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

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

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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

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

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 21 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#) 25 OCT 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 754

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

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US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2022 23:59

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

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

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

US3472096

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 09 DEC 2022 00:01

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

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US3472096

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:46:48

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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		02 MAR 2021 09:53:07

---

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 DEC 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3472096

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:02:25

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3472096

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

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* \_\_\_\_\_

US3472096

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 31 MAR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3472096

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 20 APR 2021

---

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

---

Folder OID VISIT4

---

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) 20 APR 2021

Time of assessment (00:00-23:59) 12:12 (24 HR)

Vital Signs Date and Time (derived) 20 APR 2021 12:12

Temperature (xxx.x) 36.8 C

Route of measurement Oral   
Axillary   
Other

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

Pulse (xxx) 73 beats/min

Pulse units BPM

Respiratory Rate (xxx) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 139 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 83 mmHg

Diastolic Blood Pressure units MMHG

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

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

US3472096

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

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.*

---

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 20 APR 2021

---

Collection time (*00:00-23:59*) 12:20 (24 HR)

---

Collection date and time (derived) 20 APR 2021 12:20

---

US3472096

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

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* \_\_\_\_\_

US3472096

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Date of Contact	09 NOV 2020
Time of Contact	09:45
Date and Time of Contact (derived)	09 NOV 2020 09:45
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

300 of 2598

EAB) (1725)

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

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

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

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

---

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

---

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

---

Temperature	98.1 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003 EAB) (1725)	304 of 2598
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US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

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

---

O2 Saturation	94 %
---------------	------

---

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

---

Temperature	100.0 F
-------------	---------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

308 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

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

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

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

---

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

---

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

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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)

312 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

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

---

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

---

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

---

Temperature	100.0 F
-------------	---------

---

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

---

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

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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)

316 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

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

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

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

---

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

---

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

---

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

---

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

---

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

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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

320 of 2598

EAB) (1725)

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Symptom Day

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

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

---

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

---

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

---

Temperature	99 F
-------------	------

---

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

---

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

---

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

---

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

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

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

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

---

O2 Saturation	95 %
---------------	------

---

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

---

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

---

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

---

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

---

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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

328 of 2598

EAB) (1725)

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

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

---

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

---

O2 Saturation Units	%
---------------------	---

---

Temperature	98.4 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

332 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

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

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	97 %
---------------	------

---

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

336 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	97 %
---------------	------

---

O2 Saturation Units	%
---------------------	---

---

Temperature	97.2 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003

340 of 2598

EAB) (1725)

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	99 %
---------------	------

---

O2 Saturation Units	%
---------------------	---

---

Temperature	98.0 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

344 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	97 %
---------------	------

---

O2 Saturation Units	%
---------------------	---

---

Temperature	98.2 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

348 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	98 %
---------------	------

---

O2 Saturation Units	%
---------------------	---

---

Temperature	97.2 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

352 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

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

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	23 NOV 2020
------	-------------

---

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"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

356 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	24 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	99 %
---------------	------

---

O2 Saturation Units	%
---------------------	---

---

Temperature	98.2 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

360 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

---

Date	25 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	99 %
---------------	------

---

O2 Saturation Units	%
---------------------	---

---

Temperature	98.4 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

364 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	99 %
---------------	------

---

O2 Saturation Units	%
---------------------	---

---

Temperature	98.2 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003

EAB) (1725)

368 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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"/>

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	97 %
---------------	------

---

O2 Saturation Units	%
---------------------	---

---

Temperature	97.6 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

372 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

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

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

	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 NOV 2020
------	-------------

---

Assessment Not Done	False
---------------------	-------

---

O2 Saturation	98 %
---------------	------

---

O2 Saturation Units	%
---------------------	---

---

Temperature	98.2 F
-------------	--------

---

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

---

Cough	None	<input 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)

376 of 2598

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Date of Visit 10 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes   
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes   
No

Date of Test 10 NOV 2020

Type of Test Performed Nasopharyngeal Swab   
Nasal Swab   
Saliva Test   
Other

Other, specify \_\_\_\_\_

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes   
No

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes   
No

COVID-19 Positive (CSA Programming Field Only) 1

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes   
No

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes   
No

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes   
No

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes   
No

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes   
No

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes   
No

Start Date \_\_\_\_\_

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 \_\_\_\_\_

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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 \_\_\_\_\_

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

[Generate Next COVID-19 Assessment](#)

Yes

No

---

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 May 2021 19:11:28

Generated On: 11 Aug 2021 22:46:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 NOV 2020
Day 5	Yes	13 NOV 2020
Day 7	Yes	16 NOV 2020
Day 9	Yes	18 NOV 2020
Day 14	Yes	23 NOV 2020
Day 21	Yes	30 NOV 2020
Day 28	No	

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

---

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	13:15 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 13:15
Height ( <i>xxx.x</i> )	ND - Not Done
Weight ( <i>xxx.x</i> )	ND - Not Done
Temperature ( <i>xxx.x</i> )	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
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)	_____

US3472096

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

10 NOV 2020

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3472096

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

10 NOV 2020

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) \_\_\_\_\_

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID SICKD28

---

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

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) \_\_\_\_\_

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

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.*

---

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

Was Blood Sample Taken for Immunologic Assessment of SARS\_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection \_\_\_\_\_

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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	UNBLND_DECIDE

---

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Date of updated informed consent ( <i>dd MMM yyyy</i> )	5 FEB 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> )	5 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 type="radio"/> Not Administered <input checked="" 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

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

---

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

---

---

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

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)	5 FEB 2021
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 11:02
Temperature (xxx.x)	36.8 C
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

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)	5 FEB 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 14:15
Temperature (xxx.x)	36.8 C
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

5 FEB 2021

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

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) 5 FEB 2021

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 13:50

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

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 5 FEB 2021

---

Collection time (*00:00-23:59*) 11:12 (24 HR)

---

Collection date and time (derived) 5 FEB 2021 11:12

---

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 5 FEB 2021

---

Collection time (*00:00 - 23:59*) 11:06

---

Collection Date and Time (derived) 5 FEB 2021 11:06

---

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

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*

---

---

US3472096

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

---

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

---

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:30 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 11:30
Temperature ( <i>xxx.x</i> )	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	67 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	13:39 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 13:39
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	59 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	85 mmHg
Diastolic Blood Pressure units	MMHG

US3472096

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

9 MAR 2021

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3472096

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

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) 9 MAR 2021

What was the treatment time? (00:00-23:59) 13:09 (24 HR)

Treatment Date and Time (derived) 9 MAR 2021 13:09

Which arm was used to give treatment? Left Arm   
Right Arm

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3472096

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

17 MAR 2021

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

*If Contact Not Made, please provide Comments*

US3472096

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 19:11:31

Generated On: 11 Aug 2021 22:46:48

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

---

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	20 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	12:12 (24 HR)
Vital Signs Date and Time (derived)	20 APR 2021 12:12
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	73 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3472096

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

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.*

---

US3472096

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 19:11:29

Generated On: 11 Aug 2021 22:46:48

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 20 APR 2021

---

Collection time (*00:00-23:59*) 12:20 (24 HR)

---

Collection date and time (derived) 20 APR 2021 12:20

---

US3472096

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Mar 2021 16:11:29

Generated On: 11 Aug 2021 22:46:48

AEID	USA-US122-2020-MRNA-1273-P30 1000003
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)	09 NOV 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)	29 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

418 of 2598

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Mar 2021 16:11:29

Generated On: 11 Aug 2021 22:46:48

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 <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Mar 2021 16:11:29

Generated On: 11 Aug 2021 22:46:48

AEID	
Adverse event	ELEVATED BLOOD PRESSURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 FEB 2021
Start time (00:00-23:59)	12:00 (24 HR)
AE start date and time (derived)	5 FEB 2021 12:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

420 of 2598

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Mar 2021 16:11:29

Generated On: 11 Aug 2021 22:46:48

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related   
Related   
Not Applicable

Relationship to Study Procedure Not Related   
Related   
Not Applicable

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

Other action taken (check all that apply) None

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with Sequelae   
Recovering/Resolving   
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative PARTICIPANT HAS SCHEDULED AN APPOINTMENT WITH A CARDIOLOGIST FOR MARCH 25TH, 2021

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)

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

---

**If Yes, please complete Prior/Concomitant Medication and Vaccination form.**

---

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication IBUPROFEN

Prophylaxis Yes   
No

Indication GENERALIZED PAIN

Dose per administration 400

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

423 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

	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 2000

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication TEGRETOL

Prophylaxis Yes   
No

Indication BPD

Dose per administration 400

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

425 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

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 2000

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication ZOLOFT

Prophylaxis Yes   
No

Indication BPD

Dose per administration 200

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

427 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

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 SEP 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication DYMISTA NASAL SPRAY

Prophylaxis Yes   
No

Indication ALLERGIC RHINITIS

Dose per administration 2

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify SPRAYS

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

429 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

	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) UN UNK 2000

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication ALLERGY SHOTS

Prophylaxis Yes   
No

Indication ALLERGIC RHINITIS

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify INJECTION

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

431 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

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   
No

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication KETOCONAZOLE CREAM

Prophylaxis Yes   
No

Indication SEBORRHEIC DERMITITIS

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify APPLICATION

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

433 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

	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 2017

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes   
No

Indication INFLUENZA PROPHYLAXIS

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

435 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

	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*) 21 OCT 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 21 OCT 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication VITAMIN D3

Prophylaxis Yes   
No

Indication SUPPLEMENT

Dose per administration 5000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

437 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

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) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication VITAMIN C

Prophylaxis Yes   
No

Indication SUPPLEMENT

Dose per administration 1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

439 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

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*) 10 NOV 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication ZINC LOZENGES

Prophylaxis Yes   
No

Indication SUPPLEMENT

Dose per administration UNK

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

441 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

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*) 10 NOV 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication AZITHROMYCIN

Prophylaxis Yes   
No

Indication COVID-19

Dose per administration 500

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

443 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

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*) 12 NOV 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 12 NOV 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication ALBUTEROL

Prophylaxis Yes   
No

Indication COVID-19

Dose per administration 180

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

445 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 12 NOV 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 29 NOV 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication ACETAMINOPHEN

Prophylaxis Yes   
No

Indication PAIN AT INJECTION SITE

Dose per administration 650

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

447 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

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*) 6 FEB 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 6 FEB 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

Name of Medication LISINOPRIL

Prophylaxis Yes   
No

Indication ELEVATED BLOOD PRESSURE

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

449 of 2598

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 May 2021 19:11:26

Generated On: 11 Aug 2021 22:46:48

---

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*) 18 MAR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3472096

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 May 2021 19:11:27

Generated On: 11 Aug 2021 22:46:48

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 May 2021 19:11:28

Generated On: 11 Aug 2021 22:46:48

---

Date of dosing discontinuation (dd MMM yyyy) 09 NOV 2020

---

Primary reason for dosing discontinuation

- AE (specify)
- SAE (specify)
- Death
- Lost To Follow-up
- Physician decision (specify)
- Pregnancy
- Protocol deviation (specify)
- Study Terminated By Sponsor
- Withdrawal of consent by participant (specify)
- Due to SARS-COV-2
- Other

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify \_\_\_\_\_

---

US3472096

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:46:48

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

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

SAEID	USA-US122-2020-MRNA-1273-P30 1000003
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	_____
Investigator's Last Name	_____
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

SAEID USA-US122-2020-MRNA-1273-P30  
1000003

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name \_\_\_\_\_

Investigator's Last Name \_\_\_\_\_

Site Address: Street \_\_\_\_\_

Site Address: City \_\_\_\_\_

Site Address: State \_\_\_\_\_

Site Address: Postal Code \_\_\_\_\_

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 3

Date of submission (Pre-filled from custom function) 16/NOV/2020 14:54

**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

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

SAEID USA-US122-2020-MRNA-1273-P30  
1000003

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name \_\_\_\_\_

Investigator's Last Name \_\_\_\_\_

Site Address: Street \_\_\_\_\_

Site Address: City \_\_\_\_\_

Site Address: State \_\_\_\_\_

Site Address: Postal Code \_\_\_\_\_

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 3

Date of submission (Pre-filled from custom function) 30/NOV/2020 21:40

**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

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 02 May 2021 19:11:30

Generated On: 11 Aug 2021 22:46:48

SAEID USA-US122-2020-MRNA-1273-P30  
1000003

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name \_\_\_\_\_

Investigator's Last Name \_\_\_\_\_

Site Address: Street \_\_\_\_\_

Site Address: City \_\_\_\_\_

Site Address: State \_\_\_\_\_

Site Address: Postal Code \_\_\_\_\_

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 3

Date of submission (Pre-filled from custom function) 01/DEC/2020 13:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.** True

Audit

US3472096 (Prod: Penn Prevention - (CRS))

US3472096

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:46:48**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:06
User entered 'US3472096'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 15:22:51

US3472096

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:31
User entered 'Yes (Y)'		07 Oct 2020 17:12:24

US3472096

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:31
User entered '07 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 15:22:53

US3472096

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:31
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Oct 2020 17:12:24

US3472096

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'SCRN'	System	07 Oct 2020 17:12:24

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered (b) (6) 1978'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 15:22:54

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '42'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'YEARS'	System	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '42'	System	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered 'Male (M)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:46:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 00:35:37
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:35:22

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered '7 Oct 2020'		07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Oct 2020'	System	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2020'	System	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 17:32:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 17:32:54
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	Jie Ho (b) (4)	07 Oct 2020 17:32:54
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 17:12:35
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered 'Yes (Y)'		07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered empty.		07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered empty.		07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered 'No (N)'		07 Oct 2020 17:12:35

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 15:22:53

US3472096

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:46:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '1'	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:46:48

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:45
User entered 'Yes (Y)'		07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:46:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:50
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:42:40

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Psychiatric disorders, HLGT: Personality disorders and disturbances in behaviour, HLT: Personality disorders with dramatic behaviour (Cluster B), PT: Borderline personality disorder, LLT: Borderline personality disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:48:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:48:56
Data point term sent to Coder	System	07 Oct 2020 18:43:54
User entered 'Borderline personality disorder'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Jan 2000'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 2000'	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2000'	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:46:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:43:21

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 13:30:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 13:30:40
Data point term sent to Coder	System	07 Oct 2020 18:45:05
User entered 'Herniated disc, L5-S1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 2005'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Sep 2005'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Sep 2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:46:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2005'	System	07 Oct 2020 18:44:26

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:24:12
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)	13 Jan 2021 21:05:03
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 'Procedure due to Cholecystitis, which has been updated in MH' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:30:12
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:29:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:29:14
Data point term sent to Coder	System	12 Jan 2021 17:28:06
DataPoint Un-verified.	(b) (4), (b) (6)	12 Jan 2021 17:27:28
Coding entries removed.	(b) (4), (b) (6)	12 Jan 2021 17:27:28
User entered 'cholecystectomy' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Jan 2021 17:27:28
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).	(b) (4), (b) (6)	12 Jan 2021 06:35:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 18:51:16

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	07 Oct 2020 18:51:16 07 Oct 2020 18:45:06
User entered 'Cholecystectomy'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Oct 2019'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).		13 Nov 2020 04:38:06
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Updated.' (Site from DM).	Jie Ho (b) (4)	27 Oct 2020 02:53:14
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	27 Oct 2020 02:52:40
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:31:31
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un Oct 2019' reason for change: Data Entry Error	Jie Ho (b) (4)	27 Oct 2020 02:52:40
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Oct 2019'	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2019'	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Oct 2019'	System	27 Oct 2020 02:52:40
User entered empty.	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:46:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2019'	System	27 Oct 2020 02:52:40
User entered empty.	System	07 Oct 2020 18:45:04

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:54:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:54:09
Data point term sent to Coder	System	07 Oct 2020 18:46:09
User entered 'Seasonal allergic rhinitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 1996'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 1996'	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '1996'	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:46:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:45:33

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLG: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Seborrheic dermatitis, LLT: Seborrheic dermatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:59:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:59:23
Data point term sent to Coder	System	07 Oct 2020 18:47:13
User entered 'Seborrheic dermititis, perioral'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 2017'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 2017'	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2017'	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:46:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:46:17

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:56:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 18:56:15
Data point term sent to Coder	System	07 Oct 2020 18:47:13
User entered 'obesity'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'un UNK 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:35:55
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Jan 2020'	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2020'	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:46:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered empty.	System	07 Oct 2020 18:46:34

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:24:12
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 17:29:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 17:29:55
Data point term sent to Coder	System	12 Jan 2021 17:29:11
User entered 'Cholecystitis'	(b) (4), (b) (6)	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:24:12
User entered 'UN Sep 2019'		12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:24:12
User entered '0'		12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:24:12
User entered 'No (N)'		12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:24:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Jan 2021 17:28:44
User entered 'UN Oct 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 17:28:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Jan 2021 17:28:25
User entered 'UN ' (non-conformant).	(b) (4), (b) (6)	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:24:12
User entered '0'		12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Sep 2019'	System	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2019'	System	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'Oct 2019'	System	12 Jan 2021 17:28:44
User entered empty.	System	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:46:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '2019'	System	12 Jan 2021 17:28:44
User entered empty.	System	12 Jan 2021 17:28:25

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '11:27'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '7 Oct 2020 11:27'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '190.5' cm	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
DataPoint set to visible.	(b) (4) System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered '126' kg	Petra Alexander (b) (4)	07 Oct 2020 18:37:15
DataPoint set to visible.	(b) (4) System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered '34.72007'	System	07 Oct 2020 18:37:15
DataPoint set to visible.	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'kg/m2'	System	07 Oct 2020 18:37:15
DataPoint set to visible.	System	07 Oct 2020 17:12:40

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'bpm'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'breaths/min'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'mmHg'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:24
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User entered 'mmHg'	System	07 Oct 2020 18:37:15

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41

US3472096

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41

US3472096

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:29
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:47

US3472096

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:29
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:37:47

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

**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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

**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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:38:58
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:38:38
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered 'IT'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

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)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered '1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '0'	Petra Alexander (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:29:41
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:36:35
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:38:38

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:01
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:39:17

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:01
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:39:17

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[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 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:01
User entered 'Clinic (Clinic)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:39:17

US3472096

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'VISIT1'	System	07 Oct 2020 18:39:17

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered '07 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 16:12:41

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered '116343'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 16:12:41

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Oct 2020 16:12:41

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

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)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

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)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:36

US3472096

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:48

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:06
User entered 'No (N)'	Petra Alexander (b) (4)	07 Oct 2020 18:47:36
DataPoint set to visible.	(b) (4) System	07 Oct 2020 17:32:54

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User accepted default value 'Pre-Dose (PREDOSE)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '11:27'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 11:27'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '37.3' C	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Oral (Oral)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '75'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'bpm'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '16'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'breaths/min'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '165'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'mmHg'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '93'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'mmHg'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered missing code ND - Not Done.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User accepted default value 'Post-Dose (POSTDOSE)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '13:23'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 13:23'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '37.1' C	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered 'Oral (Oral)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '69'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'bpm'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '16'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'breaths/min'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '155'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'mmHg'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:15
User entered '88'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'mmHg'	System	07 Oct 2020 18:40:52

US3472096

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:21
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:01

US3472096

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:21
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:01

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered empty.		07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered empty.		07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered '7 Oct 2020'		07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered '13:01'		07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 13:01'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:27
User entered 'Right Arm (RIGHT ARM)'		07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
DataPoint Verified.		19 Nov 2020 15:37:27
User entered 'ONCE'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 17:13:05

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:34
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:14

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:34
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:14

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:34
User entered '11:55'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:14

US3472096

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 11:55'	System	07 Oct 2020 18:41:14

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered '7 Oct 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered '11:47'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '7 Oct 2020 11:47'	System	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:40
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered empty.	System	07 Oct 2020 18:41:33

US3472096

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:37:46
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:41:43

US3472096

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:27:05
User entered '1'	System	07 Oct 2020 18:41:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:25:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered 'Yes (Y)'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:25:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered '98.8'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered 'No (N)'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:04', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c7fec297-e77b-4f98-9041-0f4cfbbf84b4'	System	07 Oct 2020 17:26:08
User entered '07 Oct 2020 13:26'	System	07 Oct 2020 17:26:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 13:21'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 15:51'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:02:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered 'Yes (Y)'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:03:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered '98.5'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:03:05', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered 'No (N)'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T18:03:08', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd8fbad45-84c5-4b82-a24b-771fe7ca4666'	System	07 Oct 2020 22:03:13
User entered '07 Oct 2020 18:03'	System	07 Oct 2020 22:03:13

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 16:46'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 2'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:34:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered 'Yes (Y)'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered '97.5'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered 'No (N)'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '540387b6-cc75-41ff-bc9c-5918c0b947ee'	System	08 Oct 2020 16:35:51
User entered '08 Oct 2020 12:35'	System	08 Oct 2020 16:35:51

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 3'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:28:48', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered 'Yes (Y)'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:29:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered '98.2'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:29:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1'	System	09 Oct 2020 20:29:58
User entered 'No (N)'	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T16:29:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '440f4ff5-9c61-4a3e-945c-997abd279fd1' User entered '09 Oct 2020 16:29'	System	09 Oct 2020 20:29:58
	System	09 Oct 2020 20:29:58

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 4'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb'	System	11 Oct 2020 00:43:44
User entered 'Yes (Y)'	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:27', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb' User entered '98.3'	System	11 Oct 2020 00:43:44
	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:41', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb'	System	11 Oct 2020 00:43:44
User entered 'No (N)'	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:43:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9ce9c1ab-e1ed-4895-9307-b3475156ddeb' User entered '10 Oct 2020 20:43'	System	11 Oct 2020 00:43:44
	System	11 Oct 2020 00:43:44

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 5'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered 'Yes (Y)'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '98.3'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered 'Yes (Y)'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:54:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	11 Oct 2020 23:06:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '1'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '0'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:06:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'd3a50f93-82cd-4e8c-88b4-b4bb74c1fd47'	System	11 Oct 2020 23:06:43
User entered '11 Oct 2020 19:06'	System	11 Oct 2020 23:06:43

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 6'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered 'Yes (Y)'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:40', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '97.3'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered 'Yes (Y)'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:01
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 19:39:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Oct 2020 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '1'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '0'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:48', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a2a5930c-dec4-4837-899e-206ff7018915'	System	12 Oct 2020 16:45:50
User entered '12 Oct 2020 12:45'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 7'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered 'Yes (Y)'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6' User entered '98.2'	System	14 Oct 2020 00:48:37
	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:27', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered 'Yes (Y)'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Oct 2020 00:48:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '1'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6'	System	14 Oct 2020 00:48:37
User entered '0'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:32', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e771b026-f9fd-4fde-8fa4-9456db2530e6' User entered '13 Oct 2020 20:48'	System	14 Oct 2020 00:48:37
	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	12 Oct 2020 16:45:50
User entered 'Day 8'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered 'Yes (Y)'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:43', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '97.3'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered 'Yes (Y)'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Oct 2020 16:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '1'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '0'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9a39379f-1ec6-40cb-8f2c-45a33fe161a5'	System	14 Oct 2020 16:37:57
User entered '14 Oct 2020 12:37'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	14 Oct 2020 00:48:37
User entered 'Day 9'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:21', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '98.2'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered 'Yes (Y)'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Not taken for solicited AE. See con med log entry for ibuprofen.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 14:55:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Oct 2020 00:06:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '1'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '0'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:38', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8bea3a1c-616e-4d04-b9c1-203c94920211'	System	16 Oct 2020 00:06:45
User entered '15 Oct 2020 20:06'	System	16 Oct 2020 00:06:45

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	14 Oct 2020 16:37:57
User entered 'Day 10'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:46:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f'	System	16 Oct 2020 18:29:08
User entered 'Yes (Y)'	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:46:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f' User entered '98.4'	System	16 Oct 2020 18:29:08
	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:46:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:29:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f'	System	16 Oct 2020 18:29:08
User entered 'No (N)'	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:29:03', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '34fce8b8-fc89-497d-9c08-8a048ee32b1f' User entered '16 Oct 2020 14:29'	System	16 Oct 2020 18:29:08
	System	16 Oct 2020 18:29:08

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'No (N)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'No (N)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered 'None (1)'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:26:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e724ce1e-f96e-41c9-bfab-ae3c7a9099d'	System	07 Oct 2020 17:26:57
User entered '07 Oct 2020 13:26'	System	07 Oct 2020 17:26:57

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 13:21'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 15:51'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:18', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'None (1)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'No (N)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'No (N)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:40', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered 'None (1)'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:42', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '31ae4180-7cb3-41f2-ab84-9b3f85cf4826'	System	07 Oct 2020 21:52:48
User entered '07 Oct 2020 17:52'	System	07 Oct 2020 21:52:48

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 16:46'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 2'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:35:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'None (1)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:46:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:11', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'No (N)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:46:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'No (N)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:26', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered 'None (1)'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '3aeb4973-725d-4c67-b935-dc0f71f9d1c4'	System	08 Oct 2020 16:36:31
User entered '08 Oct 2020 12:36'	System	08 Oct 2020 16:36:31

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 3'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:58', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'None (1)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:46:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'No (N)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:46:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'No (N)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:15', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered 'None (1)'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:03:17', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a96eb221-0337-4241-a5b6-5bd2678e9e88'	System	09 Oct 2020 16:03:23
User entered '09 Oct 2020 12:03'	System	09 Oct 2020 16:03:23

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 4'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:41', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'None (1)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:46:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'No (N)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:46:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'No (N)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f'	System	11 Oct 2020 00:42:54
User entered 'None (1)'	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'f52cf053-3666-4615-b27b-5cea7a46cc5f' User entered '10 Oct 2020 20:42'	System	11 Oct 2020 00:42:54
	System	11 Oct 2020 00:42:54

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 5'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'None (1)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:46:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'No (N)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:46:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'No (N)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered 'None (1)'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T19:05:38', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6737ea39-02f1-4658-afbd-53fa5ea8c425'	System	11 Oct 2020 23:05:40
User entered '11 Oct 2020 19:05'	System	11 Oct 2020 23:05:40

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 6'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'None (1)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:46:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'No (N)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:46:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:56', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'No (N)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:45:58', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered 'None (1)'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:01', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'e5004e9b-983a-498c-aa18-cda644be7479'	System	12 Oct 2020 16:46:03
User entered '12 Oct 2020 12:46'	System	12 Oct 2020 16:46:03

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 7'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'None (1)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:46:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:38', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'No (N)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:46:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:40', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'No (N)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:42', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered 'None (1)'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'b2dfeab5-cc38-4fa1-844d-15fe83bc0b73'	System	14 Oct 2020 00:48:46
User entered '13 Oct 2020 20:48'	System	14 Oct 2020 00:48:46

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:16', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:21', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:23', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'None (0)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf'	System	07 Oct 2020 17:27:38
User entered 'No (N)'	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T13:27:32', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '5eb5b223-a7b5-4e2b-ace9-c937f2f9f3bf' User entered '07 Oct 2020 13:27'	System	07 Oct 2020 17:27:38
	System	07 Oct 2020 17:27:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 13:21'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 15:51'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:52:56', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:01', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:03', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:05', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'None (0)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:10', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered 'No (N)'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-07T17:53:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '83adb766-b866-43b4-ac4f-590a5d7e113e'	System	07 Oct 2020 21:53:15
User entered '07 Oct 2020 17:53'	System	07 Oct 2020 21:53:15

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '07 Oct 2020 16:46'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 2'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:42', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'None (0)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered 'No (N)'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-08T12:36:51', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '03263a4e-c609-45b0-b103-66a1a542febc'	System	08 Oct 2020 16:36:53
User entered '08 Oct 2020 12:36'	System	08 Oct 2020 16:36:53

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 3'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:20', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'Some interference with activity (2)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:36', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'None (0)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:39', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered 'No (N)'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-09T12:02:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'a41fa4c5-327a-478b-ab0f-60b82e7a6067'	System	09 Oct 2020 16:02:48
User entered '09 Oct 2020 12:02'	System	09 Oct 2020 16:02:48

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 4'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:19', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:23', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'Some interference with activity (2)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:27', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:30', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'None (0)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:34', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered 'No (N)'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-10T20:42:37', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '88897bd3-63d7-4281-ad1f-9747647a9e94'	System	11 Oct 2020 00:42:40
User entered '10 Oct 2020 20:42'	System	11 Oct 2020 00:42:40

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 5'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:17', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:20', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:22', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:24', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:26', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'None (0)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520'	System	11 Oct 2020 21:47:38
User entered 'No (N)'	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-11T17:47:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'ae11ce70-2816-43a7-8c14-e80231b33520' User entered '11 Oct 2020 17:47'	System	11 Oct 2020 21:47:38
	System	11 Oct 2020 21:47:38

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 6'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:04', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:07', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'No interference with activity (1)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:09', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:11', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:13', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'None (0)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:21', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered 'No (N)'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-12T12:46:23', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '33d1d9a1-2731-4495-8afa-013b7e1126f9'	System	12 Oct 2020 16:46:27
User entered '12 Oct 2020 12:46'	System	12 Oct 2020 16:46:27

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	07 Oct 2020 17:13:05
User entered 'Day 7'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:51', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:55', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:48:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'None (0)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:49:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered 'No (N)'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-13T20:49:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2678de08-2826-4485-bd7b-6ede734f50cc'	System	14 Oct 2020 00:49:04
User entered '13 Oct 2020 20:49'	System	14 Oct 2020 00:49:04

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:13:05

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	12 Oct 2020 16:45:50
User entered 'Day 8'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:32', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '48f30f7b-4f8d-4c5e-8a4f-d3d04c5543ce'	System	14 Oct 2020 16:37:37
User entered 'No (N)'	System	14 Oct 2020 16:37:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-14T12:37:35', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '48f30f7b-4f8d-4c5e-8a4f-d3d04c5543ce'	System	14 Oct 2020 16:37:37
User entered '14 Oct 2020 12:37'	System	14 Oct 2020 16:37:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:45:50

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	14 Oct 2020 00:48:37
User entered 'Day 9'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'afeffa1e-60d2-4ae9-b38c-eb3702e25261'	System	16 Oct 2020 00:06:56
User entered 'No (N)'	System	16 Oct 2020 00:06:56

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-15T20:06:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'afeffa1e-60d2-4ae9-b38c-eb3702e25261'	System	16 Oct 2020 00:06:56
User entered '15 Oct 2020 20:06'	System	16 Oct 2020 00:06:56

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:48:37

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
Data entry locked.	System	14 Oct 2020 16:37:57
User entered 'Day 10'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:46:48

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 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '275b81b5-ff55-4d47-8517-b1cd758f5387'	System	16 Oct 2020 18:28:51
User entered 'No (N)'	System	16 Oct 2020 18:28:51

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-10-16T14:28:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '275b81b5-ff55-4d47-8517-b1cd758f5387' User entered '16 Oct 2020 14:28'	System	16 Oct 2020 18:28:51
	System	16 Oct 2020 18:28:51

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:37:57

US3472096

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 22:46:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:24:11
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:37:57

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered 'Yes (Y)'		14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered '14 Oct 2020'		14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered 'Contact Made (CONTACT MADE)'		14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:38:18
User entered empty.		14 Oct 2020 22:47:49

US3472096

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:38:23
User entered 'Yes (Y)'		14 Oct 2020 22:47:54

US3472096

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:54
User entered '1'	System	14 Oct 2020 22:47:54

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered 'Yes (Y)'		21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered '21 Oct 2020'		21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered 'Contact Made (CONTACT MADE)'		21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:59:55
User entered empty.		21 Oct 2020 17:56:32

US3472096

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:01
User entered 'Yes (Y)'		21 Oct 2020 17:56:35

US3472096

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:12
User entered '1'	System	21 Oct 2020 17:56:35

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered 'Yes (Y)'		30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered '30 Oct 2020'		30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered 'Contact Made (CONTACT MADE)'		30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:07
User entered empty.		30 Oct 2020 20:51:49

US3472096

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:00:11
User entered 'Yes (Y)'		30 Oct 2020 20:51:52

US3472096

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:19
User entered '1'	System	30 Oct 2020 20:51:52

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:23
User entered 'Yes (Y)'		04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:23
User entered '04 Nov 2020'		04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[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 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:23
User entered 'Clinic (Clinic)'		04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'VISIT2'	System	04 Nov 2020 16:26:04

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User accepted default value 'Pre-Dose (PREDOSE)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '04 Nov 2020'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '11:02'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered '04 Nov 2020 11:02'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '36.5' C	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered 'Oral (Oral)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '69'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'bpm'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '17'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'breaths/min'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '170'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'mmHg'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered '91'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'mmHg'	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User accepted default value 'Post-Dose (POSTDOSE)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered 'No (N)'	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:28
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:26:21

US3472096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:34
User entered 'Yes (Y)'		04 Nov 2020 16:26:15

US3472096

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:34
User entered '04 Nov 2020'		04 Nov 2020 16:26:15

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered 'No (N)'	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered 'Other (OTHER)'	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered 'Participant needed to leave for another appointment.'	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 23:58:40
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered empty.	System	23 Nov 2020 04:25:24

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:46
User entered 'Yes (Y)'		04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:46
User entered '04 Nov 2020'		04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:46
User entered '11:09'		04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered '04 Nov 2020 11:09'	System	04 Nov 2020 16:26:29

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered '04 Nov 2020'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered 'Yes (Y)'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered '11:06'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:46:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered '04 Nov 2020 11:06'	System	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered 'No (N)'		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:58:52
User entered empty.		04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:46:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered empty.	System	04 Nov 2020 16:26:45

US3472096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:59:01
User entered 'Yes (Y)'		04 Nov 2020 16:26:50

US3472096

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered '1'	System	04 Nov 2020 16:26:50

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:17:43
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:11:18

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.		08 Apr 2021 14:17:43
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:11:18

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:17:43
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:11:18

US3472096

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:17:43
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:11:18

US3472096

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:17:50
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:36

US3472096

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered '1'	System	09 Dec 2020 16:12:36

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	[REDACTED]	08 Apr 2021 14:17:55
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:45

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	[REDACTED]	08 Apr 2021 14:17:55
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:45

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:17:55
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:45

US3472096

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:17:55
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:45

US3472096

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:17:59
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:49

US3472096

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered '1'	System	09 Dec 2020 16:12:49

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:58

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:58

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:58

US3472096

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:18:12
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Participant on illness track'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:12:58

US3472096

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:18
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 16:13:01

US3472096

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered '1'	System	09 Dec 2020 16:13:01

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:31
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Dec 2020 17:02:54

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
DataPoint Verified.	(b) (4)	08 Apr 2021 14:18:31
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 17:02:54

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[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 20:38:46
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:18:31
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 17:02:54

US3472096

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered 'VISIT3'	System	27 Dec 2020 17:02:54

US3472096

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
DataPoint Verified.	[REDACTED]	08 Apr 2021 14:18:38
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED]	27 Dec 2020 17:03:07

US3472096

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:46
User entered '1'	System	27 Dec 2020 17:03:07

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2020-12-08T12:50:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9bfd55ec-9fb0-473b-a859-eb5c9766c55e'	System	08 Dec 2020 17:51:20
User entered 'No (N)'	System	08 Dec 2020 17:51:20

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2020-12-08T12:51:12', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9bfd55ec-9fb0-473b-a859-eb5c9766c55e'	System	08 Dec 2020 17:51:20
User entered 'No (N)'	System	08 Dec 2020 17:51:20

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-12-08T12:51:16', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '9bfd55ec-9fb0-473b-a859-eb5c9766c55e'	System	08 Dec 2020 17:51:20
User entered '08 Dec 2020 12:51:16'	System	08 Dec 2020 17:51:20

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2020-12-11T16:16:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6d9b402c-2133-4172-b100-6316de939278'	System	11 Dec 2020 21:16:55
User entered 'No (N)'	System	11 Dec 2020 21:16:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2020-12-11T16:16:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6d9b402c-2133-4172-b100-6316de939278'	System	11 Dec 2020 21:16:55
User entered 'No (N)'	System	11 Dec 2020 21:16:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-12-11T16:16:52', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '6d9b402c-2133-4172-b100-6316de939278'	System	11 Dec 2020 21:16:55
User entered '11 Dec 2020 16:16:52'	System	11 Dec 2020 21:16:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2020-12-27T12:07:25', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c07db9af-f212-471b-8d7d-358015ae4c01'	System	27 Dec 2020 17:07:39
User entered 'No (N)'	System	27 Dec 2020 17:07:39

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2020-12-27T12:07:28', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c07db9af-f212-471b-8d7d-358015ae4c01'	System	27 Dec 2020 17:07:39
User entered 'No (N)'	System	27 Dec 2020 17:07:39

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2020-12-27T12:07:33', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'c07db9af-f212-471b-8d7d-358015ae4c01'	System	27 Dec 2020 17:07:39
User entered '27 Dec 2020 12:07:33'	System	27 Dec 2020 17:07:39

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-04T13:29:26', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bb21ec81-795c-4494-aec6-aad4f76d8d8d'	System	04 Jan 2021 18:29:34
User entered 'No (N)'	System	04 Jan 2021 18:29:34

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-04T13:29:29', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bb21ec81-795c-4494-aec6-aad4f76d8d8d'	System	04 Jan 2021 18:29:34
User entered 'No (N)'	System	04 Jan 2021 18:29:34

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-04T13:29:31', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bb21ec81-795c-4494-aec6-aad4f76d8d8d' User entered '04 Jan 2021 13:29:31'	System	04 Jan 2021 18:29:34
	System	04 Jan 2021 18:29:34

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-08T13:34:09', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '96408f24-1e10-4a17-831b-f8a105e08597'	System	08 Jan 2021 18:34:15
User entered 'No (N)'	System	08 Jan 2021 18:34:15

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-08T13:34:11', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '96408f24-1e10-4a17-831b-f8a105e08597'	System	08 Jan 2021 18:34:15
User entered 'No (N)'	System	08 Jan 2021 18:34:15

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-08T13:34:14', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '96408f24-1e10-4a17-831b-f8a105e08597' User entered '08 Jan 2021 13:34:14'	System	08 Jan 2021 18:34:15
	System	08 Jan 2021 18:34:15

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-15T08:46:56', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '46a19432-19f1-4ba2-9c20-248f0c2c3e32'	System	15 Jan 2021 13:47:06
User entered 'No (N)'	System	15 Jan 2021 13:47:06

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-15T08:46:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '46a19432-19f1-4ba2-9c20-248f0c2c3e32'	System	15 Jan 2021 13:47:06
User entered 'No (N)'	System	15 Jan 2021 13:47:06

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-15T08:47:02', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '46a19432-19f1-4ba2-9c20-248f0c2c3e32'	System	15 Jan 2021 13:47:06
User entered '15 Jan 2021 08:47:02'	System	15 Jan 2021 13:47:06

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-22T07:18:48', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '0c506f84-708c-45c9-bc48-b618bc6d9e17'	System	22 Jan 2021 12:18:54
User entered 'No (N)'	System	22 Jan 2021 12:18:54

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-22T07:18:50', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '0c506f84-708c-45c9-bc48-b618bc6d9e17'	System	22 Jan 2021 12:18:54
User entered 'No (N)'	System	22 Jan 2021 12:18:54

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-22T07:18:53', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '0c506f84-708c-45c9-bc48-b618bc6d9e17' User entered '22 Jan 2021 07:18:53'	System	22 Jan 2021 12:18:54
	System	22 Jan 2021 12:18:54

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-01-29T07:51:47', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '68d5a97f-29b9-41b0-ae5a-5970781839e5'	System	29 Jan 2021 12:51:55
User entered 'No (N)'	System	29 Jan 2021 12:51:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-01-29T07:51:49', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '68d5a97f-29b9-41b0-ae5a-5970781839e5'	System	29 Jan 2021 12:51:55
User entered 'No (N)'	System	29 Jan 2021 12:51:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-01-29T07:51:51', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '68d5a97f-29b9-41b0-ae5a-5970781839e5' User entered '29 Jan 2021 07:51:51'	System	29 Jan 2021 12:51:55
	System	29 Jan 2021 12:51:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-02-05T22:05:41', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '28f76be3-5acf-462c-bb4e-8d4691f20433'	System	06 Feb 2021 03:06:18
User entered 'No (N)'	System	06 Feb 2021 03:06:18

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-02-05T22:05:44', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '28f76be3-5acf-462c-bb4e-8d4691f20433'	System	06 Feb 2021 03:06:18
User entered 'No (N)'	System	06 Feb 2021 03:06:18

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-02-05T22:05:46', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '28f76be3-5acf-462c-bb4e-8d4691f20433'	System	06 Feb 2021 03:06:18
User entered '05 Feb 2021 22:05:46'	System	06 Feb 2021 03:06:18

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-02-12T07:36:54', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '835adfb5-877b-450b-8407-94643e6d942d'	System	12 Feb 2021 12:37:04
User entered 'No (N)'	System	12 Feb 2021 12:37:04

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-02-12T07:36:57', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '835adfb5-877b-450b-8407-94643e6d942d'	System	12 Feb 2021 12:37:04
User entered 'No (N)'	System	12 Feb 2021 12:37:04

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-02-12T07:36:59', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '835adfb5-877b-450b-8407-94643e6d942d'	System	12 Feb 2021 12:37:04
User entered '12 Feb 2021 07:36:59'	System	12 Feb 2021 12:37:04

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-02-19T07:03:01', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '7efce5c0-20ba-4c0e-a739-a5f1a528f02e'	System	19 Feb 2021 17:10:40
User entered 'No (N)'	System	19 Feb 2021 17:10:40

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-02-19T07:03:04', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '7efce5c0-20ba-4c0e-a739-a5f1a528f02e'	System	19 Feb 2021 17:10:40
User entered 'No (N)'	System	19 Feb 2021 17:10:40

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-02-19T07:03:08', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '7efce5c0-20ba-4c0e-a739-a5f1a528f02e' User entered '19 Feb 2021 07:03:08'	System	19 Feb 2021 17:10:40
	System	19 Feb 2021 17:10:40

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-02T09:53:12-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '322e17a4-153e-4fc7-8764-af3cabe7fe70'	System	02 Mar 2021 14:53:19
User entered 'No (N)'	System	02 Mar 2021 14:53:19

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-03-02T09:53:14-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '322e17a4-153e-4fc7-8764-af3cabe7fe70'	System	02 Mar 2021 14:53:19
User entered 'No (N)'	System	02 Mar 2021 14:53:19

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-02T09:53:16-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '322e17a4-153e-4fc7-8764-af3cabe7fe70'	System	02 Mar 2021 14:53:19
User entered '02 Mar 2021 09:53:16'	System	02 Mar 2021 14:53:19

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-05T07:44:43-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '1b9338a5-c0b0-4d18-b875-39817f66aabe'	System	05 Mar 2021 12:44:48
User entered 'No (N)'	System	05 Mar 2021 12:44:48

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-03-05T07:44:46-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '1b9338a5-c0b0-4d18-b875-39817f66aabe'	System	05 Mar 2021 12:44:48
User entered 'No (N)'	System	05 Mar 2021 12:44:48

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-05T07:44:47-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '1b9338a5-c0b0-4d18-b875-39817f66aabe' User entered '05 Mar 2021 07:44:47'	System	05 Mar 2021 12:44:48
	System	05 Mar 2021 12:44:48

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-12T07:07:16-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '782377b7-4c9a-4d05-a233-be4814020117'	System	12 Mar 2021 12:07:24
User entered 'No (N)'	System	12 Mar 2021 12:07:24

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-03-12T07:07:18-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '782377b7-4c9a-4d05-a233-be4814020117'	System	12 Mar 2021 12:07:24
User entered 'No (N)'	System	12 Mar 2021 12:07:24

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-12T07:07:20-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '782377b7-4c9a-4d05-a233-be4814020117'	System	12 Mar 2021 12:07:24
User entered '12 Mar 2021 07:07:20'	System	12 Mar 2021 12:07:24

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-19T12:21:16-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'Yes (Y)'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (12282b35a699ff53)', Time: '2021-03-19T12:21:09-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'No (N)'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-19T12:21:20-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'No (N)'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (12282b35a699ff53)', Time: '2021-03-19T12:21:26-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'Yes (Y)'	System	19 Mar 2021 16:21:55

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

Please 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 (12282b35a699ff53)', Time: '2021-03-19T12:21:32-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-19T12:21:35-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '472d697b-12ee-40c0-9409-a15c756964d5'	System	19 Mar 2021 16:21:55
User entered '19 Mar 2021 12:21:35'	System	19 Mar 2021 16:21:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-03-30T12:07:26-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '36352b55-7c7d-47b0-8101-1e7aa0649bbd'	System	30 Mar 2021 16:14:10
User entered 'No (N)'	System	30 Mar 2021 16:14:10

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-03-30T12:07:28-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '36352b55-7c7d-47b0-8101-1e7aa0649bbd'	System	30 Mar 2021 16:14:10
User entered 'No (N)'	System	30 Mar 2021 16:14:10

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-03-30T12:07:30-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '36352b55-7c7d-47b0-8101-1e7aa0649bbd'	System	30 Mar 2021 16:14:10
User entered '30 Mar 2021 12:07:30'	System	30 Mar 2021 16:14:10

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-06T10:22:43-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bdbelb8b-67f4-4b41-8e9b-9aae70a41ab3'	System	06 Apr 2021 14:22:55
User entered 'No (N)'	System	06 Apr 2021 14:22:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-06T10:22:47-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bdb1b8b-67f4-4b41-8e9b-9aae70a41ab3'	System	06 Apr 2021 14:22:55
User entered 'No (N)'	System	06 Apr 2021 14:22:55

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-06T10:22:49-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: 'bdbelb8b-67f4-4b41-8e9b-9aae70a41ab3'	System	06 Apr 2021 14:22:55
User entered '06 Apr 2021 10:22:49'	System	06 Apr 2021 14:22:55

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-13T09:37:09-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8676cbd6-0c28-47e2-ab22-794c261fe3f5'	System	13 Apr 2021 13:37:16
User entered 'No (N)'	System	13 Apr 2021 13:37:16

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-13T09:37:11-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8676cbd6-0c28-47e2-ab22-794c261fe3f5'	System	13 Apr 2021 13:37:16
User entered 'No (N)'	System	13 Apr 2021 13:37:16

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-13T09:37:14-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8676cbd6-0c28-47e2-ab22-794c261fe3f5'	System	13 Apr 2021 13:37:16
User entered '13 Apr 2021 09:37:14'	System	13 Apr 2021 13:37:16

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-16T07:31:02-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '23c2cbb8-0596-484e-93bc-89006cbea2d8'	System	16 Apr 2021 11:31:09
User entered 'No (N)'	System	16 Apr 2021 11:31:09

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-16T07:31:04-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '23c2cbb8-0596-484e-93bc-89006cbea2d8'	System	16 Apr 2021 11:31:09
User entered 'No (N)'	System	16 Apr 2021 11:31:09

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-16T07:31:07-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '23c2cbb8-0596-484e-93bc-89006cbea2d8'	System	16 Apr 2021 11:31:09
User entered '16 Apr 2021 07:31:07'	System	16 Apr 2021 11:31:09

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-23T07:22:21-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8335883c-bbfd-4de5-8025-e9e4413bb0f1'	System	23 Apr 2021 11:22:27
User entered 'No (N)'	System	23 Apr 2021 11:22:27

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-23T07:22:23-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8335883c-bbfd-4de5-8025-e9e4413bb0f1'	System	23 Apr 2021 11:22:27
User entered 'No (N)'	System	23 Apr 2021 11:22:27

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-23T07:22:24-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '8335883c-bbfd-4de5-8025-e9e4413bb0f1'	System	23 Apr 2021 11:22:27
User entered '23 Apr 2021 07:22:24'	System	23 Apr 2021 11:22:27

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[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 (ee74d16e068d803b)', Time: '2021-04-30T06:48:00-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '348a9f95-98af-496e-95d6-e7367388120d'	System	30 Apr 2021 10:48:07
User entered 'No (N)'	System	30 Apr 2021 10:48:07

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

Have you been exposed to someone with 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 (ee74d16e068d803b)', Time: '2021-04-30T06:48:01-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '348a9f95-98af-496e-95d6-e7367388120d'	System	30 Apr 2021 10:48:07
User entered 'No (N)'	System	30 Apr 2021 10:48:07

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee74d16e068d803b)', Time: '2021-04-30T06:48:04-04:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '348a9f95-98af-496e-95d6-e7367388120d'	System	30 Apr 2021 10:48:07
User entered '30 Apr 2021 06:48:04'	System	30 Apr 2021 10:48:07

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 11:57:14

**US3472096**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:46:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 11:57:14

US3472096

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:57:14
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 11:57:14

US3472096

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:46:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:48:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-02T09:53:05-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2698389f-5988-4853-b1e4-2ddf84857c06'	System	02 Mar 2021 14:53:09
User entered 'No (N)'	System	02 Mar 2021 14:53:09

US3472096

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:46:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:48:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12282b35a699ff53)', Time: '2021-03-02T09:53:07-05:00', User OID: 'PatientReportedOutcome (US3472096)', ODM File OID: '2698389f-5988-4853-b1e4-2ddf84857c06'	System	02 Mar 2021 14:53:09
User entered '02 Mar 2021 09:53:07'	System	02 Mar 2021 14:53:09

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:58:33
User entered 'Yes (Y)'		27 Dec 2020 17:15:32

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:58:33
User entered '27 Dec 2020'		27 Dec 2020 17:15:32

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:58:33
User entered 'Contact Made (CONTACT MADE)'		27 Dec 2020 17:15:32

US3472096

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:58:33
User entered empty.		27 Dec 2020 17:15:32

US3472096

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:58:37
User entered 'Yes (Y)'		27 Dec 2020 17:15:37

US3472096

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:45
User entered 'I'	System	27 Dec 2020 17:15:37

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:15:38
User entered 'Yes (Y)'		30 Jan 2021 21:02:00

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:15:38
User entered '30 Jan 2021'		30 Jan 2021 21:02:00

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:15:38
User entered 'Contact Made (CONTACT MADE)'		30 Jan 2021 21:02:00

US3472096

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:15:38
User entered empty.		30 Jan 2021 21:02:00

US3472096

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:15:44
User entered 'Yes (Y)'		30 Jan 2021 21:02:18

US3472096

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:06:51
User entered '1'	System	30 Jan 2021 21:02:18

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:17
User entered 'No (N)'		18 Mar 2021 14:41:54

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:17
User entered empty.		18 Mar 2021 14:41:54

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:17
User entered empty.		18 Mar 2021 14:41:54

US3472096

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:17
User entered empty.		18 Mar 2021 14:41:54

US3472096

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:21
User entered 'Yes (Y)'		18 Mar 2021 14:41:58

US3472096

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:13:43
User entered '1'	System	18 Mar 2021 14:41:58

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 01:32:30

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:30
User entered '31 Mar 2021'		01 Apr 2021 01:32:30

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:30
User entered 'Contact Made (CONTACT MADE)'		01 Apr 2021 01:32:30

US3472096

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:30
User entered empty.		01 Apr 2021 01:32:30

US3472096

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:16:34
User entered 'Yes (Y)'		01 Apr 2021 01:32:36

US3472096

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:00:36
User entered '1'	System	01 Apr 2021 01:32:36

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:36:40

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:36:40

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:36:40

US3472096

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

---

Audit	User	Time (GMT)
User entered 'VISIT4'	System	21 Apr 2021 17:36:40

---

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '12:12'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '20 Apr 2021 12:12'	System	21 Apr 2021 17:37:39

---

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '73'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Apr 2021 17:37:39

---

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Apr 2021 17:37:39

---

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '139'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 17:37:39

---

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '83'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 17:37:39

US3472096

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:54

US3472096

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:37:54

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:38:06

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:38:06

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '12:20'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:38:06

US3472096

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Collection date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '20 Apr 2021 12:20'	System	21 Apr 2021 17:38:06

---

US3472096

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:38:12

US3472096

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:38:12

---

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (09NOV2020). Please review and reconcile ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 10:02:50
Query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (09NOV2020). Please review and reconcile ' answered with 'data is accurate' (Site from DM).	(b) (4)	06 Jan 2021 14:25:41
User opened query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (09NOV2020). Please review and reconcile ' (Site from DM).	(b) (4)	05 Jan 2021 19:43:54
DataPoint Verified.	(b) (4)	19 Nov 2020 15:44:54
User closed query 'Re-query: It is to be completed upon learning of positive result. If there is any new information it is to be updated within 24 hrs. Please review training slides sent to sites on 04Sep2020.' (Site from CRA).	(b) (4)	17 Nov 2020 02:13:33
Query 'Re-query: It is to be completed upon learning of positive result. If there is any new information it is to be updated within 24 hrs. Please review training slides sent to sites on 04Sep2020.' answered with 'Thanks for your guidance. I personally did not receive a slide deck on 04SEP2020 but I will check with our CRA to see what this refers to. Severity Assessment completed.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 16:38:40
User opened query 'Re-query: It is to be completed upon learning of positive result. If there is any new information it is to be updated within 24 hrs. Please review training slides sent to sites on 04Sep2020.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:34:37
User closed query 'Please reconcile and add severity page as required.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:34:37

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Please reconcile and add severity page as required.' answered with 'We are in communication with our CRA to determine exactly when the severity assessment needs to be completed as it is unclear to us after review of the protocol and CCGs.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:20:52
User opened query 'Please reconcile and add severity page as required.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:42:07
User entered '09 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:54
User entered '09:45'		10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '09 Nov 2020 09:45'	System	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:54
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:46:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:15:49

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4) (b) (4)	02 May 2021 19:11:33
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:55:19
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User closed query 'Re-query: Per CCGs and training provided to all sites on 04Sep2020 first day of symptom log = first day subject experiences symptoms. Please correct log as previously requested.' (Site from CRA).		17 Nov 2020 02:12:43
Query 'Re-query: Per CCGs and training provided to all sites on 04Sep2020 first day of symptom log = first day subject experiences symptoms. Please correct log as previously requested.' answered with 'Updated the Symptom log to accurately reflect Symptom Day.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 16:55:39
User opened query 'Re-query: Per CCGs and training provided to all sites on 04Sep2020 first day of symptom log = first day subject experiences symptoms. Please correct log as previously requested.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:35:33
User closed query 'Please reconcile log. Symptom Day 1 = first day subject experienced symptoms' (Site from CRA).		16 Nov 2020 12:35:33
Query 'Please reconcile log. Symptom Day 1 = first day subject experienced symptoms' answered with 'Per protocol, Day 1 is the Illness Visit.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 02:54:52
User opened query 'Please reconcile log. Symptom Day 1 = first day subject experienced symptoms' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:42:30
User entered '10 Nov 2020'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.1' F		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		10 Nov 2020 20:16:33

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
	(b) (4)	
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:11
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:55:19
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98.1' F		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		12 Nov 2020 16:15:35

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4) (b) (4)	02 May 2021 19:11:33
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:55:19
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '12 Nov 2020'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '94'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '100.0' F		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		13 Nov 2020 18:14:08

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
	(b) (4)	
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '13 Nov 2020'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.1' F		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:40:54

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4) (b) (4)	02 May 2021 19:11:33
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '14 Nov 2020'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '100.0' F		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:42:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Please add Day 1 to line 7. If not assessed because it was before subject called site it should be recorded with day symptoms started and checked for assessment not done' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 23:32:49
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:49
Query 'Please add Day 1 to line 7. If not assessed because it was before subject called site it should be recorded with day symptoms started and checked for assessment not done' answered with 'Updated.' (Site from CRA).	Jie Ho (b) (4)	17 Nov 2020 03:17:13
User opened query 'Please add Day 1 to line 7. If not assessed because it was before subject called site it should be recorded with day symptoms started and checked for assessment not done' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:12:33
User entered '15 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.0' F		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		16 Nov 2020 20:47:26

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4) (b) (4)	02 May 2021 19:11:33
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Jie Ho (b) (4)	17 Nov 2020 03:16:04
User entered 'Day 1 (Day 1)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '09 Nov 2020'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered missing code ND - Not Done.	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99' F	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Not Done (Not Done)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	Jie Ho (b) (4)	17 Nov 2020 03:10:02

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '16 Nov 2020'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '95'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '99.0' F		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:16:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Jie Ho (b) (4)	24 Nov 2020 16:10:01
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '17 Nov 2020'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98.4' F		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		18 Nov 2020 17:17:41

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 18Nov2020. Please review data and consider updating to 'Day 10' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 16:12:22
Query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 18Nov2020. Please review data and consider updating to 'Day 10' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:19:53
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 13:19:42
User opened query 'Per CDM: Per sponsor review, 'Symptom Days' are out of sequence starting on 18Nov2020. Please review data and consider updating to 'Day 10' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 21:54:20
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '18 Nov 2020'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '0'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '97'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered '98.9' F		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Mild (Mild)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'		19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	9 Nov 2020 15:48:49
User entered 'Mild (Mild)'		9 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:49
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 14:39:17

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4)	22 Nov 2020 22:10:18
User entered 'Day 2 (Day 2)'	(b) (4)	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '19 Nov 2020'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97.2' F		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		20 Nov 2020 13:19:25

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 13 (Day 13)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '20 Nov 2020'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '99'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.0' F		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:10:18

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 14 (Day 14)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '21 Nov 2020'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.2' F		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		22 Nov 2020 22:11:03

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 15 (Day 15)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '22 Nov 2020'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97.2' F		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		23 Nov 2020 00:32:20

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 16 (Day 16)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '23 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '99'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97.5' F		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		24 Nov 2020 17:48:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 17 (Day 17)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '24 Nov 2020'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '99'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.2' F		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		25 Nov 2020 00:29:00

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 18 (Day 18)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '25 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '99'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.4' F		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:15:07

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 19 (Day 19)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '26 Nov 2020'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '99'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.2' F		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:18:12

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:19:42
User entered 'Day 20 (Day 20)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '27 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '97.6' F		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'Mild (Mild)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:21:28

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 13:20:07
User entered 'Day 21 (Day 21)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '28 Nov 2020'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '0'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '%'	System	01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered '98.2' F		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	15 Feb 2021 14:27:34
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:46:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:34
User entered 'None (None)'		01 Dec 2020 18:22:46

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered '10 Nov 2020'		10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[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 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered 'Yes (Y)'		10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[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 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
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)	17 Nov 2020 14:51:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 14:51:04
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 'AE added to Log.' (Site from System).	Jie Ho (b) (4)	16 Nov 2020 03:25:58
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	12 Nov 2020 22:35:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 22:35:22
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:16:56
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:16:52
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered '10 Nov 2020'		10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered empty.		10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[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 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:39:33
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:39:23
User entered 'No (N)' reason for change: Data Entry Jie Ho Error	(b) (4)	12 Nov 2020 22:39:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 22:39:23
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:17:10
User entered 'PENDING' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:17:10
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:16:52
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:44:30
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	12 Nov 2020 22:39:33
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:17:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:17:10
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 20:16:52
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:16:52

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:46:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User entered '1'	System	12 Nov 2020 22:35:22

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[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 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:52:25
User entered '93' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:51:32
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 16:31:40
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:31:40
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
User closed query 'Per ETRTR: Please complete all missing fields on this page. Thanks!' (Site from CRA).		02 Apr 2021 13:39:27
Query 'Per ETRTR: Please complete all missing fields on this page. Thanks!' answered with 'Updated.' (Site from CRA).	Jie Ho (b) (4)	04 Dec 2020 17:13:41
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:07
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:07
User opened query 'Per ETRTR: Please complete all missing fields on this page. Thanks!' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 15:03:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Evidence of Shock Requires Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:39:43
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

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Generated On: 11 Aug 2021 22:46:48

[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:39:57
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:29
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 13:40:10
DataPoint Un-verified.	Jie Ho (b) (4)	04 Dec 2020 17:13:34
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	04 Dec 2020 17:13:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
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US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[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 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 16:31:40
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 16:31:40
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:31:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:46:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:29
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 16:31:29

US3472096

Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:46:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:13:02
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:27:51
User entered 'No (N)'	Jie Ho (b) (4)	04 Dec 2020 17:46:16

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '12 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 20:38:05
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Per ETRTR: Date of collection for Day 5 is one day after Day 3. Please confirm Date of collection and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	15 Feb 2021 14:30:21
Query 'Per ETRTR: Date of collection for Day 5 is one day after Day 3. Please confirm Date of collection and update if applicable.' answered with 'This is the correct date. Sample pick up could not be arranged for 11/14/2020 so sample was collected on 11/13/2020.' (Site from CRA).	Jie Ho (b) (4)	03 Dec 2020 19:08:32
User opened query 'Per ETRTR: Date of collection for Day 5 is one day after Day 3. Please confirm Date of collection and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 14:59:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:38:05
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	19 Nov 2020 14:38:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '16 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 14:38:00
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:11
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 14:38:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered '18 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 14:38:00
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:13:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:13:21
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:13:21
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:13:21
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 18:28:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:28:06
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:30:29
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 18:28:06
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:28:06
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:46:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:46:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:30:29
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 18:03:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 18:03:13
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	03 Dec 2020 18:03:13
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 18:03:07
DataPoint Un-verified.	Jie Ho (b) (4)	03 Dec 2020 18:03:07
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	03 Dec 2020 18:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:14:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 03:14:06
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:14:06
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:13:45
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:11
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:13:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:38
User closed query 'Please reconcile and add saliva page' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:33:39
Query 'Please reconcile and add saliva page' answered with 'Saliva log updated.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:14:27
User opened query 'Please reconcile and add saliva page' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:41:41
User entered 'Yes (Y)'		10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:38
User entered '10 Nov 2020'		10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:38
User entered 'Home (Home)'	(b) (4), (b) (6)	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

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Audit	User	Time (GMT)
User entered 'SICKD1'	System	10 Nov 2020 20:17:45

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US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '10 Nov 2020'		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:46:46
User entered '13:15'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered '10 Nov 2020 13:15'	System	10 Nov 2020 20:18:11

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US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 20:18:11
DataPoint set to visible.	System	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 20:18:11
DataPoint set to visible.	System	10 Nov 2020 20:17:45

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '99.1' F		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered empty.		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '80'		10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

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Audit	User	Time (GMT)
User entered 'bpm'	System	10 Nov 2020 20:18:11

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US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered '17'	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Nov 2020 20:18:11

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US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:18:11

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US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:46
User entered missing code ND - Not Done.	(b) (4)	10 Nov 2020 20:18:11

US3472096

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:18:11

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US3472096

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:46:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:18:17

US3472096

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:46:56
User entered '10 Nov 2020'		10 Nov 2020 20:18:17

US3472096

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:46:48

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:03
User entered 'Yes (Y)'		10 Nov 2020 20:18:24

US3472096

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:03
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:18:24

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:20:20
User entered 'No (N)'		01 Mar 2021 15:07:53

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:20
User entered empty.		01 Mar 2021 15:07:53

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:20
User entered empty.		01 Mar 2021 15:07:53

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

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Audit	User	Time (GMT)
User entered 'SICKD28'	System	01 Mar 2021 15:07:53

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US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered 'No (N)'		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

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US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

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US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

---

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

---

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:26
User entered empty.		01 Mar 2021 15:08:02

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 15:08:02

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US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:30
User entered 'No (N)'		01 Mar 2021 15:08:07

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:20:30
User entered empty.		01 Mar 2021 15:08:07

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:46:48

Was Blood Sample Taken for Immunologic Assessment of SARS\_COV-2 Infection?

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 15:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 13:14:59
Query 'Data is required. Please complete.' answered with 'erroneously entered to D28' (Site from System).	Jie Ho (b) (4)	16 Nov 2020 03:18:27
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 03:18:11
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:18:11
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:17:49

US3472096

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:46:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:20:36
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	16 Nov 2020 03:18:11
User entered '10 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:17:49

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:04:55
User entered 'Yes (Y)'		06 Feb 2021 04:58:40

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:04:55
User entered '5 Feb 2021'		06 Feb 2021 04:58:40

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:04:55
User entered 'Clinic (Clinic)'		06 Feb 2021 04:58:40

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'UNBLND_DECIDE'	System	06 Feb 2021 04:58:40

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered '5 Feb 2021'		06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:25:44

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered 'Yes (Y)'		06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:25:44

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered '5 Feb 2021'		06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered 'Placebo (Placebo)'		06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered 'Not Administered (NA)'		06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:00
User entered 'Yes (Y)'		06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '1'	System	06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:46:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '1'	System	06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered empty.	System	06 Feb 2021 05:02:27
DataPoint set to visible.	System	06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered empty.	System	06 Feb 2021 05:02:27
DataPoint set to visible.	System	06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User accepted default value 'Pre-Dose (PREDOSE)'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered 'Yes (Y)'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '5 Feb 2021'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '11:02'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 11:02'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '36.8' C		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered 'Oral (Oral)'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered empty.		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '74'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'bpm'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '12'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'breaths/min'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '166'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mmHg'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '93'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mmHg'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:46:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered empty.	System	06 Feb 2021 05:02:27
DataPoint set to visible.	System	06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '5 Feb 2021'	(b) (4), (b) (6)	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '14:15'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 14:15'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '36.8' C		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered 'Oral (Oral)'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered empty.		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '80'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'bpm'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '14'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'breaths/min'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '156'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mmHg'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:06
User entered '86'		06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mmHg'	System	06 Feb 2021 05:02:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 05:02:35

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:11
User entered '5 Feb 2021'		06 Feb 2021 05:02:35

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered 'Yes (Y)'		06 Feb 2021 05:03:00

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered empty.	(b) (4), (b) (6)	06 Feb 2021 05:03:00

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered empty.		06 Feb 2021 05:03:00

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'mRNA-1273'	System	06 Feb 2021 05:03:00
DataPoint set to visible.	System	06 Feb 2021 04:59:27

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered '5 Feb 2021'		06 Feb 2021 05:03:00

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered '13:50'		06 Feb 2021 05:03:00

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 13:50'	System	06 Feb 2021 05:03:00

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered 'Right Arm (RIGHT ARM)'		06 Feb 2021 05:03:00

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:17
User entered 'ONCE'	System	06 Feb 2021 05:03:00

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered 'INTRAMUSCULAR'	System	06 Feb 2021 05:03:00

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:22
User entered 'Yes (Y)'		06 Feb 2021 05:03:16

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:22
User entered '5 Feb 2021'	(b) (4), (b) (6)	06 Feb 2021 05:03:16

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:22
User entered '11:12'		06 Feb 2021 05:03:16

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 11:12'	System	06 Feb 2021 05:03:16

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:26
User entered 'Yes (Y)'		06 Feb 2021 05:03:33

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:46:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:26
User entered '5 Feb 2021'		06 Feb 2021 05:03:33

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:26
User entered '11:06'		06 Feb 2021 05:03:33

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:46:48

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '5 Feb 2021 11:06'	System	06 Feb 2021 05:03:33

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:05:32
User entered 'Yes (Y)'		06 Feb 2021 05:03:38

US3472096

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:49:18
User entered '1'	System	06 Feb 2021 05:03:38

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:11:22
User entered 'Yes (Y)'		11 Feb 2021 18:08:18

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:11:22
User entered '12 Feb 2021' reason for change: Data Entry Error		12 Feb 2021 18:22:05
User entered '11 Feb 2021'		11 Feb 2021 18:08:18

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:11:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Feb 2021 18:08:18

US3472096

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:11:22
User entered empty.		11 Feb 2021 18:08:18

US3472096

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:10:55
User entered 'Yes (Y)'		11 Feb 2021 18:08:24

US3472096

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User entered '1'	System	11 Feb 2021 18:08:24

US3472096

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:17:10
User entered '1'	System	11 Feb 2021 18:08:24
DataPoint set to visible.	System	11 Feb 2021 18:08:24

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:19
User entered 'Yes (Y)'		10 Mar 2021 18:53:57

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:19
User entered '9 Mar 2021'		10 Mar 2021 18:53:57

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:19
User entered 'Clinic (Clinic)'		10 Mar 2021 18:53:57

US3472096

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'OLD29'	System	10 Mar 2021 18:53:57

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered 'Yes (Y)'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '9 Mar 2021'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '11:30'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered '9 Mar 2021 11:30'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '36.3' C		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered 'Oral (Oral)'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered empty.		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '67'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'bpm'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '16'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'breaths/min'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '144'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mmHg'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '90'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mmHg'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered 'Yes (Y)'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '9 Mar 2021'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '13:39'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered '9 Mar 2021 13:39'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '36.6' C		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered 'Oral (Oral)'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered empty.		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '59'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'bpm'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '16'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'breaths/min'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '144'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mmHg'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:30
User entered '85'		10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mmHg'	System	10 Mar 2021 18:55:49

US3472096

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:34
User entered 'Yes (Y)'		10 Mar 2021 18:56:15

US3472096

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:34
User entered '9 Mar 2021'		10 Mar 2021 18:56:15

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:41
User entered 'Yes (Y)'		10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:41
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

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 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:41
User entered empty.		10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'mRNA-1273'	System	10 Mar 2021 18:56:39
DataPoint set to visible.	System	11 Feb 2021 18:08:24

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:41
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:41
User entered '13:09'		10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered '9 Mar 2021 13:09'	System	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:41
User entered 'Right Arm (RIGHT ARM)'		10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
DataPoint Verified.		08 Apr 2021 14:12:41
User entered 'ONCE'	System	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 18:56:39

US3472096

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:46
User entered 'Yes (Y)'		10 Mar 2021 18:57:00

US3472096

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:18:29
User entered '1'	System	10 Mar 2021 18:57:00

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:54
User entered 'Yes (Y)'		17 Mar 2021 23:51:28

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:54
User entered '17 Mar 2021'		17 Mar 2021 23:51:28

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Mar 2021 23:51:28

US3472096

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:46:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:54
User entered empty.		17 Mar 2021 23:51:28

US3472096

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:12:58
User entered 'Yes (Y)'		17 Mar 2021 23:51:40

US3472096

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:46:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:39
User entered '1'	System	17 Mar 2021 23:51:40

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:49:51

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:49:51

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:49:51

US3472096

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:46:48

[Folder OID](#)

---

Audit	User	Time (GMT)
User entered 'OLD57'	System	20 Apr 2021 22:49:51

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US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '12:12'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Vital Signs Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '20 Apr 2021 12:12'	System	20 Apr 2021 22:50:53

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US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '73'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Apr 2021 22:50:53

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US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Apr 2021 22:50:53

---

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '139'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 22:50:53

---

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '83'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:53

US3472096

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:46:48

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 22:50:53

---

US3472096

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:58

US3472096

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:46:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:50:58

US3472096

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:51:11

US3472096

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:51:11

US3472096

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User entered '12:20'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:51:11

US3472096

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:46:48

[Collection date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered '20 Apr 2021 12:20'	System	20 Apr 2021 22:51:11

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US3472096

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:46:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:36:56
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 06:08:29
Query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'This has a corresponding AE - elevated blood pressure, which is already in the AE log in the EDC.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:32:02
User opened query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:09:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:36
User closed query 'Please reconcile and add COVID 19 as central lab provided positive illness results' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 12:37:06

US3472096

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:46:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Please reconcile and add COVID 19 as central lab provided positive illness results' answered with 'Updated AE log.' (Site from CRA).	Jie Ho (b) (4)	16 Nov 2020 03:32:25
User opened query 'Please reconcile and add COVID 19 as central lab provided positive illness results' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 22:41:27
User entered 'Yes (Y)'		10 Nov 2020 20:18:46

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:53:58
User entered 'USA-US122-2020-mRNA-1273-P301000003'	System	16 Nov 2020 19:53:36
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 19:53:36

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
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) (b) (4)	16 Nov 2020 03:26:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:26:02
Data point term sent to Coder	System	16 Nov 2020 03:25:09
User entered 'COVID-19'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'PV Query: The start date of the event is 09 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 09 Nov 2020 to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:40:14
Query 'PV Query: The start date of the event is 09 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 09 Nov 2020 to the COVID-19 assessment symptom log in EDC.' answered with '09Nov2020 is on the symptom log..please clarify.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:21:34
User opened query 'PV Query: The start date of the event is 09 Nov 2020. Did the subject report any symptoms on that day? If yes, please add 09 Nov 2020 to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:46:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '09 Nov 2020'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 03:24:37

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US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:28:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:28:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:28:39
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:28:39
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:40:11
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'This is marked ongoing..please clarify query.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:22:14
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:45:48
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 03:24:37

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US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'No (N)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Death

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:40:07
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' answered with 'Updated.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:27:23
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:46:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Related (RELATED)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Not Related (NOT RELATED)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:40:05
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 15:33:15
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Reason was changed to "Due to SARSCOV2. ' (Site from System).	Jie Ho (b) (4)	23 Nov 2020 04:29:46
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'Updated.' (Site from Safety).	Jie Ho (b) (4)	23 Nov 2020 04:28:02
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Nov 2020 04:27:41
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:27:15
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:47:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Not Applicable (NOT APPLICABLE)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '1'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered '0'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:28:39
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:40:02
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'we will respond when his symptoms resolve.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 15:35:32
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:28:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:28:34
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:46:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:28
User entered empty.	Jie Ho (b) (4)	16 Nov 2020 03:24:37

US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 03:24:37

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US3472096

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:46:48

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 03:24:37

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US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:59:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:59:55
Data point term sent to Coder	System	10 Mar 2021 18:59:41
User entered 'Elevated blood pressure'	(b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 20:14:08
User entered '12:00' reason for change: Data Entry Error	System	15 Mar 2021 20:14:08
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 18:59:24
User entered empty.	System	10 Mar 2021 18:59:24
	(b) (4), (b) (6)	

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Feb 2021 12:00'	System	15 Mar 2021 20:14:08
User entered empty.	System	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Mar 2021 19:00:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:00:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:00:45
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 18:59:24
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Mar 2021 19:00:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:00:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:00:45
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 18:59:24
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Mar 2021 19:00:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:00:45
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:00:45
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 18:59:24
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:01
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 16:11:29
User entered 'Participant has scheduled an appointment with a cardiologist for March 25th, 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:59:24

US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 18:59:24

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US3472096

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:46:48

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 18:59:24

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:46:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:53:45
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:48
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:47:49

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
Un-reviewed for Data Management.	(b) (4)	01 Feb 2021 08:13:14
Reviewed for Data Management.	(b) (4), (b) (6)	01 Feb 2021 08:13:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 17:27:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 17:27:14
Data point term sent to Coder	System	10 Dec 2020 17:25:38
Coding entries removed.	Jie Ho (b) (4)	10 Dec 2020 17:24:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Dec 2020 01:00:05
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 Dec 2020 01:00:05
Data point term sent to Coder	System	06 Dec 2020 00:58:49
Coding entries removed.	(b) (4), (b) (6)	06 Dec 2020 00:58:09
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:39:24
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 Oct 2020 07:39:24
Data point term sent to Coder	System	07 Oct 2020 18:49:18
User entered 'ibuprofen'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).		01 Feb 2021 09:23:41
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Reported conmed ibuprofen is not taken for any diagnosed condition. It is taken prn as noted for isolated events of generalized pain and indication was determined by PI not to be reportable as per protocol' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:18:49
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 05:16:36
User closed query 'Per CDM re-query: Per previous query, please update the Indication to record what this medication is being taken as prophylactic for and review and reconcile response to 'Prophylaxis' as it is currently NO.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 14:01:46
Query 'Per CDM re-query: Per previous query, please update the Indication to record what this medication is being taken as prophylactic for and review and reconcile response to 'Prophylaxis' as it is currently NO.' answered with 'This was incorrectly updated.' (Site from DM).	Jie Ho (b) (4)	10 Dec 2020 17:25:01
User entered 'Generalized Pain' reason for change: Per Query Resolution	Jie Ho (b) (4)	10 Dec 2020 17:24:49

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Per previous query, please update the Indication to record what this medication is being taken as prophylactic for and review and reconcile response to 'Prophylaxis' as it is currently NO.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:01:55
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. 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)	09 Dec 2020 16:01:55
DataPoint Un-verified.	(b) (4), (b) (6)	06 Dec 2020 00:58:09
User entered 'prophylactic' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Dec 2020 00:58:09
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'prophylactic' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 00:57:54
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. 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)	27 Nov 2020 08:50:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed pain relief'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '400'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed (PRN)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2000'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:11

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:49:11

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:49:11

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:49:11

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CARBAMAZEPINE, PRODUCTSYNONYM: TEGRETOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 21:45:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 21:45:59
Data point term sent to Coder	System	07 Oct 2020 18:50:20
User entered 'tegretol'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'BPD'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '400'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2000'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 18:49:56

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:49:56

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:49:56

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:49:56

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:28:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:28:50
Data point term sent to Coder	System	07 Oct 2020 19:42:21
User entered 'zoloft'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'BPD'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '200'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '01 Sep 2020'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:42:19

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:42:19

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:42:19

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 19:42:19

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE, PRODUCTSYNONYM: DYMISTA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	11 Dec 2020 07:54:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 07:54:07
Data point term sent to Coder	System	06 Dec 2020 01:42:53
Coding entries removed.	(b) (4), (b) (6)	06 Dec 2020 01:42:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE, PRODUCTSYNONYM: DYMISTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Oct 2020 14:54:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Oct 2020 14:54:20
Data point term sent to Coder	System	07 Oct 2020 19:43:25
User entered 'Dymista nasal spray'	Petra Alexander (b) (4)	07 Oct 2020 19:43:16
	(b) (4)	

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Allergic rhinitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '2'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'sprays'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:02:13
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate. ' answered with 'Nasal' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 01:42:52
DataPoint Un-verified.	(b) (4), (b) (6)	06 Dec 2020 01:42:36
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Dec 2020 01:42:36
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:51:07
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2000'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:43:16

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:43:16

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:43:16

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 19:43:16

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: VARIOUS, ATC: ALLERGENS, ATC: ALLERGENS, ATC: ALLERGEN EXTRACTS, PRODUCT: ALLERGENS NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:14:44
Data point term sent to Coder	System	07 Oct 2020 19:44:28
User entered 'Allergy shots'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'allergic rhinitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Injection'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'every month (QM)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Subcutaneous (SUBCUTANEOUS)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2016'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:44:05

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:44:05

---

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:44:05

---

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '802 (802)'	System	07 Oct 2020 19:44:05

---

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:01:22
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 Oct 2020 07:01:22
Data point term sent to Coder	System	07 Oct 2020 19:45:33
User entered 'ketoconazole cream'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Seborrheic dermatitis'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '1'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Application'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed (PRN)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Topical (TOPICAL)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'un UNK 2017'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:45:04

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:45:04

---

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:45:04

---

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:45:04

---

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:54:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:54:25
Data point term sent to Coder	System	04 Nov 2020 16:38:57
Data point term sent to Coder	System	04 Nov 2020 16:28:42
User entered 'Influenza vaccination'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Influenza prophylaxis'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0.5'		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mL (mL)'		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 16:38:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 16:38:24
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 16:38:24
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 16:27:48
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '21 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '21 Oct 2020'		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'		04 Nov 2020 16:27:48

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:27:48

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:27:48

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 16:27:48

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
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) (b) (4)	12 Nov 2020 16:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:18:32
Data point term sent to Coder	System	12 Nov 2020 16:18:13
User entered 'Vitamin D3'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'		12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Supplement'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '5000'		12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'IU (IU)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'		12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 16:17:23

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:23

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:23

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:17:23

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:18:32
Data point term sent to Coder User entered 'Vitamin C'	System (b) (4), (b) (6)	12 Nov 2020 16:18:13 12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Supplement'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '1000'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '10 Nov 2020'		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'		12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 16:17:46

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:46

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:17:46

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:17:46

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:55:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:55:39
Data point term sent to Coder	System	12 Nov 2020 16:18:13
User entered 'Zinc lozenges'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Supplement'		12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'UNK'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once daily (QD)'		12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'		12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:18:09

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'		12 Nov 2020 16:18:09

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:18:09

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:18:09

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:18:09

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:03:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:03:36
Data point term sent to Coder	System	12 Nov 2020 23:03:09
User entered 'Azithromycin'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'		12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'COVID-19'		12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '500'		12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '12 Nov 2020'		12 Nov 2020 23:02:34

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 23:02:34

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:02:34

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:02:34

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:02:34

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:12:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:12:41
Data point term sent to Coder	System	12 Nov 2020 23:04:10
User entered 'Albuterol'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'COVID-19'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '180'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:30:20
User entered 'ug (ug)' reason for change: Data Entry	Jie Ho (b) (4)	23 Nov 2020 04:30:20
Error		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Other (OTHER)'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
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)	23 Nov 2020 15:33:35
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).	Jie Ho (b) (4)	23 Nov 2020 04:30:28
DataPoint Un-verified.	Jie Ho (b) (4)	23 Nov 2020 04:30:20
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	23 Nov 2020 04:30:20
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)	20 Nov 2020 13:53:18
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'mcg'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 18:29:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:29:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	31 Mar 2021 13:22:16
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 18:29:26
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 18:29:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered 'No (N)'		12 Nov 2020 23:03:42

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:03:42

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:03:42

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:46:48

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:03:42

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:12:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 18:12:55
Data point term sent to Coder	System	11 Feb 2021 18:12:29
User entered 'Acetaminophen'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'No (N)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 13:57:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Per protocol, indication not reportable as AE for part B' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:45:31
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:38:38
User entered 'Pain at injection site'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered '650'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'mg (mg)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'once (ONCE)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'Oral (ORAL)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered '6 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered '0'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'No (N)'		11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered '6 Feb 2021'	(b) (4)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. Otherwise, provide clarification. ' (Site from DM).		03 Mar 2021 13:57:33
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	02 Mar 2021 18:45:40
' answered with 'updated' (Site from DM). User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	02 Mar 2021 18:45:36
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. Otherwise, provide clarification. ' (Site from DM).		02 Mar 2021 08:38:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 18:12:19

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:46:48

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:12:19

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:12:19

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 18:12:19

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US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 16:21:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 16:21:46
Data point term sent to Coder User entered 'Lisinopril'	System (b) (4), (b) (6)	22 Mar 2021 16:20:16 22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'No (N)'		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'Elevated blood pressure'		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered '20'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'Oral (ORAL)'		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered '18 Mar 2021'		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered '0'		22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:20:04

US3472096

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:46:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:16
User entered 'No (N)'		22 Mar 2021 16:20:04

US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:46:48**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 16:20:04

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 16:20:04

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US3472096

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:46:48**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 16:20:04

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US3472096

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:46:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:13:47
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:41:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:41:20
User entered 'No (N)' reason for change: Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:41:20
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:41:07
User entered empty; reason for change Data Entry Error	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:41:07
User entered 'Yes (Y)'	Petra Alexander (b) (4) (b) (4)	07 Oct 2020 19:40:42

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:46:48

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:50:42
User entered '09 Nov 2020'	Jie Ho (b) (4)	23 Nov 2020 04:27:41

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:46:48

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
User closed query ' Per CDM: Reason for dose not given is 'Other' with specification "PARTICIPANT NEEDED TO LEAVE FOR ANOTHER APPOINTMENT." under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Due to SARS-COV-2'. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' (Site from DM). Query ' Per CDM: Reason for dose not given is 'Other' with specification "PARTICIPANT NEEDED TO LEAVE FOR ANOTHER APPOINTMENT." under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Due to SARS-COV-2'. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' answered with 'Both are accurate - dose was not given at that visit because participant had to leave for another appt - visit was rescheduled for a few days later, but in that interim ppt reported covid symptoms and tested positive, so could not be dosed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:20
User opened query ' Per CDM: Reason for dose not given is 'Other' with specification "PARTICIPANT NEEDED TO LEAVE FOR ANOTHER APPOINTMENT." under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Due to SARS-COV-2'. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:29:37
User opened query ' Per CDM: Reason for dose not given is 'Other' with specification "PARTICIPANT NEEDED TO LEAVE FOR ANOTHER APPOINTMENT." under exposure form under visit 2. Reason under dosing discontinuation form is selected as is 'Due to SARS-COV-2'. Please review and reconcile an appropriate reason for discontinuation in both the visits. Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:58:11
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 23:50:42
User entered 'Due to SARS-COV-2 (COVID)'	Jie Ho (b) (4)	23 Nov 2020 04:27:41

US3472096

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:46:48

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:50:42
User entered empty.	Jie Ho (b) (4)	23 Nov 2020 04:27:41

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Death

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:40:25
DataPoint Verified.		19 Nov 2020 15:39:43
User entered 'US'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 13:56:59
User entered '2'	System	30 Nov 2020 21:40:50
User entered '1'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:40:25
DataPoint Verified.		19 Nov 2020 15:39:43
User entered 'US'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 13:56:59
User entered '2'	System	30 Nov 2020 21:40:50
User entered '1'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:46:48

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:39:43
User entered '16/Nov/2020 14:54'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:46:48

**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.	Ian Frank (b) (4)	02 May 2021 19:11:33
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:40:25
DataPoint Verified.		19 Nov 2020 15:39:43
User entered '1'		16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:40:25
DataPoint Verified.		19 Nov 2020 15:39:43
User entered 'US'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 13:56:59
User entered '2'	System	30 Nov 2020 21:40:50
User entered '1'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:46:48

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:51
User entered '30/Nov/2020 21:40'	System	30 Nov 2020 21:40:50

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:46:48

**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.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:51
Reviewed for Safety.		01 Dec 2020 13:56:44
User entered '1'		30 Nov 2020 21:40:50

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'USA-US122-2020-MRNA-1273-P301000003'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

Death

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:39:43
Reviewed for Safety.		16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4)	19 Nov 2020 15:39:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 19:54:09
User entered 'No (N)'	System	16 Nov 2020 19:53:36

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 21:40:25
DataPoint Verified.		19 Nov 2020 15:39:43
User entered 'US'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:46:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 13:56:59
User entered '2'	System	30 Nov 2020 21:40:50
User entered '1'	System	16 Nov 2020 19:54:17

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:46:48

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:51
User entered '01/Dec/2020 13:56'	System	01 Dec 2020 13:56:59

US3472096

Folder: SAE USA-US122-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:46:48

**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.	Ian Frank (b) (4)	02 May 2021 19:11:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:23:51
User entered 'I'		01 Dec 2020 13:56:59