

US3342127 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:08:04

All time stamps listed in this document are displayed in GMT

US3342127

**Form: Participant Creation**

**Data signed:** (b) (4) 13 Mar 2021 15:14:11

**Generated On: 09 Jun 2021 17:08:04**

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[Participant ID](#)

US3342127

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

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US3342127

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 20 AUG 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 SCRN

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US3342127

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	64
Age Units	YEARS
Age (Derived)	64
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	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3342127

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Date of Informed Consent (*dd MMM yyyy*) 20 AUG 2020

Month and Year of Informed Consent (derived) AUG 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

US3342127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

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Did the participant meet all eligibility criteria?

Yes

No

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US3342127

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

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Were any significant conditions reported?

Yes

No

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US3342127

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342127

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Condition	HEART ARRHYTHMIA (TYPE UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342127

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Condition	DEEP VEIN THROMBOSIS
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

US3342127

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Condition	HEPATITIS B
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 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)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Condition	GUN SHOT WOUND
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Condition	CONGESTIVE HEART FAILURE
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)	_____

US3342127

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	20 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:09 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:09
Height ( <i>xxx.x</i> )	182 cm
Weight ( <i>xxx.x</i> )	79.6 kg
BMI ( <i>xxx.x</i> )	24.03091 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

20 AUG 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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US3342127

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

**Specify** GOES TO >3 STORES PER WEEK;  
RIDES PUBLIC TRANSPORT

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

<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)	True
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 20 AUG 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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US3342127

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 106186

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

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

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

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

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

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

Liver Disease Yes  No

Human Immunodeficiency Virus (HIV) infection Yes  No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

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Height	ND - Not Done
Weight	ND - Not Done

---

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

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> )	20 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:09 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:09
Temperature ( <i>xxx.x</i> )	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	50 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

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> )	20 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	12:50 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:50
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	58 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	97 mmHg
Diastolic Blood Pressure units	MMHG

US3342127

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Was the physical examination performed?

Yes

No

---

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

---

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

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US3342127

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 12:19 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 12:19

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 20 AUG 2020

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Collection time (*00:00-23:59*) 11:57 (24 HR)

---

Collection date and time (derived) 20 AUG 2020 11:57

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US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

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Collection date ( <i>dd MMM yyyy</i> )			20 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:59	20 AUG 2020 11:59
Nasopharyngeal Swab 2	No		

---

US3342127

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**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 98.3 °F

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

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

PC Time Stamp 20 AUG 2020 12:53

PC Open Date & Time 20 AUG 2020 12:39

PC Close Date & Time 20 AUG 2020 15:09

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**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 98.6 °F

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

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

PC Time Stamp	20 AUG 2020 17:55
PC Open Date & Time	20 AUG 2020 16:04
PC Close Date & Time	21 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp 21 AUG 2020 20:43

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes   
No

Please record your **TEMPERATURE** in °F \_\_\_\_\_

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 \_\_\_\_\_

To **PREVENT** pain or fever from occurring \_\_\_\_\_

PC Time Stamp \_\_\_\_\_

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes   
No

Please record your **TEMPERATURE** in °F  
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  
To **PREVENT** pain or fever from occurring  
PC Time Stamp  
PC Open Date & Time 23 AUG 2020 12:00  
PC Close Date & Time 24 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**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  
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  
To **PREVENT** pain or fever from occurring  
PC Time Stamp  
PC Open Date & Time 24 AUG 2020 12:00  
PC Close Date & Time 25 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °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	25 AUG 2020 12:34
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**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 98.5 °F

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

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

PC Time Stamp 26 AUG 2020 19:49

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**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

20 AUG 2020 12:54

PC Open Date & Time

20 AUG 2020 12:39

PC Close Date & Time

20 AUG 2020 15:09

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**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

20 AUG 2020 17:57

PC Open Date & Time

20 AUG 2020 16:04

PC Close Date & Time

21 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

3

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

Please select one response below

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

PC Time Stamp 21 AUG 2020 22:03

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**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	25 AUG 2020 12:34
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**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

26 AUG 2020 19:50

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

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

No   
Yes

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PC Time stamp	20 AUG 2020 12:55
PC Open Date & Time	20 AUG 2020 12:39
PC Close Date & Time	20 AUG 2020 15:09

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US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

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

No

Yes

PC Time stamp	20 AUG 2020 17:58
PC Open Date & Time	20 AUG 2020 16:04
PC Close Date & Time	21 AUG 2020 11:59

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

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Yes

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PC Time stamp	21 AUG 2020 22:04
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

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US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

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Yes

---

PC Time stamp

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PC Open Date & Time

22 AUG 2020 12:00

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PC Close Date & Time

23 AUG 2020 11:59

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US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Yes

---

PC Time stamp

---

PC Open Date & Time

23 AUG 2020 12:00

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PC Close Date & Time

24 AUG 2020 11:59

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US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

---

Yes

---

PC Time stamp

---

PC Open Date & Time

24 AUG 2020 12:00

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PC Close Date & Time

25 AUG 2020 11:59

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US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

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	Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 12:35
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

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US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

---

Yes

---

PC Time stamp	26 AUG 2020 19:51
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

---

US3342127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

US3342127

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 4 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3342127

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3342127

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:41:43

Generated On: 09 Jun 2021 17:08:04

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 21 SEP 2020

---

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

---

Folder OID VISIT2

---

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:41:43

Generated On: 09 Jun 2021 17:08:04

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> )	21 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:05 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:05
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:41:43

Generated On: 09 Jun 2021 17:08:04

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> )	21 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	12:43 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 12:43
Temperature ( <i>xxx.x</i> )	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	92 mmHg
Diastolic Blood Pressure units	MMHG

US3342127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:41:43

Generated On: 09 Jun 2021 17:08:04

---

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.*

---

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

Was study treatment given? Yes   
No

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 SEP 2020

What was the treatment time? (00:00-23:59) 12:12 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 12:12

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

US3342127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 21 SEP 2020

---

Collection time (*00:00-23:59*) 11:53 (24 HR)

---

Collection date and time (derived) 21 SEP 2020 11:53

---

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Collection date ( <i>dd MMM yyyy</i> )			21 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:55	21 SEP 2020 11:55
Nasopharyngeal Swab 2	No		

---

US3342127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp 21 SEP 2020 12:49

PC Open Date & Time 21 SEP 2020 12:32

PC Close Date & Time 21 SEP 2020 15:02

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

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

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

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

PC Time Stamp 21 SEP 2020 16:37  
PC Open Date & Time 21 SEP 2020 15:57  
PC Close Date & Time 22 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 99.4 °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):

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

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

PC Time Stamp 22 SEP 2020 19:19

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F  
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  
To **PREVENT** pain or fever from occurring  
PC Time Stamp  
PC Open Date & Time 23 SEP 2020 12:00  
PC Close Date & Time 24 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp 24 SEP 2020 20:23

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.4 °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	25 SEP 2020 14:05
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.4 °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 26 SEP 2020 15:07

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**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  
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  
To **PREVENT** pain or fever from occurring  
PC Time Stamp  
PC Open Date & Time 27 SEP 2020 12:00  
PC Close Date & Time 28 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

21 SEP 2020 12:50

PC Open Date & Time

21 SEP 2020 12:32

PC Close Date & Time

21 SEP 2020 15:02

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

21 SEP 2020 16:38

PC Open Date & Time

21 SEP 2020 15:57

PC Close Date & Time

22 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**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

Please record - **REDNESS AT INJECTION SITE (in mm)**

3

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

3

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

22 SEP 2020 19:22

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**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	24 SEP 2020 20:24
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**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	25 SEP 2020 14:07
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**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

26 SEP 2020 15:07

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

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

No

Yes

---

PC Time stamp	21 SEP 2020 12:51
PC Open Date & Time	21 SEP 2020 12:32
PC Close Date & Time	21 SEP 2020 15:02

---

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

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

No

Yes

---

PC Time stamp	21 SEP 2020 16:39
PC Open Date & Time	21 SEP 2020 15:57
PC Close Date & Time	22 SEP 2020 11:59

---

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

---

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 19:23
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

---

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

---

Yes

---

PC Time stamp

---

PC Open Date & Time

23 SEP 2020 12:00

---

PC Close Date & Time

24 SEP 2020 11:59

---

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

---

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 20:25
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

---

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

---

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 14:08
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

---

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

---

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 15:08
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

---

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Yes

---

PC Time stamp

---

PC Open Date & Time

27 SEP 2020 12:00

---

PC Close Date & Time

28 SEP 2020 11:59

---

US3342127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3342127

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3342127

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3342127

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:41:15

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:41:43

Generated On: 09 Jun 2021 17:08:04

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 22 OCT 2020

---

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

---

Folder OID VISIT3

---

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:41:43

Generated On: 09 Jun 2021 17:08:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	10:17 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 10:17
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:41:43

Generated On: 09 Jun 2021 17:08:04

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

22 OCT 2020

---

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

---

US3342127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:41:43

Generated On: 09 Jun 2021 17:08:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 22 OCT 2020

---

Collection time (*00:00-23:59*) 10:41 (24 HR)

---

Collection date and time (derived) 22 OCT 2020 10:41

---

US3342127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:41:43

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

---

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 OCT 2020 13:25:07
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

---

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 27 OCT 2020 04:10:41

Patient Cloud Open Date & Time 27 OCT 2020 00:01

Patient Cloud Close Date & Time 31 OCT 2020 23:59

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

---

<b>TIMEPOINT</b>	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	04 NOV 2020 16:25:39
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

---

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 17 NOV 2020 00:03:03

Patient Cloud Open Date & Time 17 NOV 2020 00:01

Patient Cloud Close Date & Time 21 NOV 2020 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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	24 NOV 2020 17:03:52
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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	30 NOV 2020 17:08:41
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 05 DEC 2020 00:11:36

Patient Cloud Open Date & Time 05 DEC 2020 00:01

Patient Cloud Close Date & Time 09 DEC 2020 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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	12 DEC 2020 02:03:10
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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	22 DEC 2020 10:06:48
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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 <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	26 DEC 2020 20:26:08
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	True
Chills	True
Cough	False
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 JAN 2021 00:05:19
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 22:42:12
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 16 JAN 2021 18:32:18

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

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

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 23 JAN 2021 03:59:00

Patient Cloud Open Date & Time 23 JAN 2021 00:01

Patient Cloud Close Date & Time 27 JAN 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 13:38:37
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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	06 FEB 2021 00:02:48
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 01:13:51
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 FEB 2021 21:33:05
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 194

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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>	27 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 MAR 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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 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	06 MAR 2021 19:49:18
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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 13 MAR 2021 00:36:47

Patient Cloud Open Date & Time 13 MAR 2021 00:01

Patient Cloud Close Date & Time 17 MAR 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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 <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	20 MAR 2021 21:24:26
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 11:06:21
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 15:41:58
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 APR 2021 06:50:13
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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<b>TIMEPOINT</b>	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 <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	21 APR 2021 15:40:40
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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<b>TIMEPOINT</b>	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 20:38:14
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

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21 JUL 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 14 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 18 AUG 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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°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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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°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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#) 29 SEP 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	09 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#) 16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 20 OCT 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 27 OCT 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 08 DEC 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#) 11 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 15 DEC 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 22 DEC 2021 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#) 12 JAN 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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

15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#) 05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#) 09 FEB 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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>	19 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 FEB 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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°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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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>	26 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAR 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

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**Generated On: 09 Jun 2021 17:08:04**

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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](#) 02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#) 06 APR 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#) 13 APR 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 2022 00:01

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[Patient Cloud Close Date & Time](#) 08 JUN 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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°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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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°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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

06 AUG 2022 00:01

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10 AUG 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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°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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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°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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#)

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#) 12 OCT 2022 23:59

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US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

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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](#) 15 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#) 19 OCT 2022 23:59

---

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**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

US3342127

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59

US3342127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:08:04

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		06 MAR 2021 19:50:04

US3342127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 NOV 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3342127

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 DEC 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3342127

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

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* \_\_\_\_\_

US3342127

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3342127

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 10 MAR 2021

---

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

---

Folder OID VISIT4

---

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 15:31:17

Generated On: 09 Jun 2021 17:08:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	09:49 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 09:49
Temperature ( <i>xxx.x</i> )	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	83 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

10 MAR 2021

---

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

---

US3342127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 10 MAR 2021

---

Collection time (*00:00-23:59*) 10:19 (24 HR)

---

Collection date and time (derived) 10 MAR 2021 10:19

---

US3342127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:14:13

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:34:58

Generated On: 09 Jun 2021 17:08:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 APR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3342127

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:34:58

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3342127

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

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* \_\_\_\_\_

US3342127

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

Date of Contact	06 JAN 2021
Time of Contact	08:30
Date and Time of Contact (derived)	06 JAN 2021 08:30
Type of Contact	Clinic Visit - Scheduled <input type="radio"/> Clinical Visit - Unscheduled <input checked="" type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	30 DEC 2020
------	-------------

---

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

---

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

---

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

---

Temperature	101.5 F
-------------	---------

---

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

---

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

---

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

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

Date 31 DEC 2020

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	01 JAN 2021
------	-------------

---

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

---

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

---

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

---

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

---

Chills	None	<input 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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	02 JAN 2021
------	-------------

---

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

---

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

---

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

---

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

---

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

---

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

---

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

---

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

Date 03 JAN 2021

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

None	<input 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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	04 JAN 2021
------	-------------

---

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

---

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

---

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

---

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

---

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

---

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

---

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

---

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

---

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	05 JAN 2021
------	-------------

---

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

---

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

---

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

---

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

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

Symptom Day

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	06 JAN 2021
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	98.3 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	7 JAN 2021
------	------------

---

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

---

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

---

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

---

Temperature	98.8 F
-------------	--------

---

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

---

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

---

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

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

Symptom Day

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	8 JAN 2021
------	------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	98.5 F
-------------	--------

---

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

---

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

---

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

---

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	9 JAN 2021
------	------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	99.1 F
-------------	--------

---

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

---

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

---

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

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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"/>

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	10 JAN 2021
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	98.1 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	11 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	98.3 F
-------------	--------

---

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

---

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

---

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

---

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

Symptom Day

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	12 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	98.6 F
-------------	--------

---

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

---

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

---

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

---

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

---

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

Symptom Day

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	13 JAN 2021
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	98.6 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	14 JAN 2021
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	98.7 F
-------------	--------

---

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

---

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

---

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

---

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

Symptom Day

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	15 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	98.6 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

Symptom Day

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	16 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	98.7 F
-------------	--------

---

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

---

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

---

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

---

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

---

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 13 Mar 2021 15:14:11

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---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

Date	17 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	98.5 F
-------------	--------

---

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

---

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

---

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

---

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

---

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

Symptom Day

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

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

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

Date 18 JAN 2021

Assessment Not Done False

O2 Saturation 98 %

O2 Saturation Units %

Temperature 98.6 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

---

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

---

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 13 Mar 2021 15:14:11

Generated On: 09 Jun 2021 17:08:04

Date of Visit 6 JAN 2021

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 6 JAN 2021

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) 0

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Mar 2021 15:08:42

Generated On: 09 Jun 2021 17:08:04

---

[Generate Next COVID-19 Assessment](#)

Yes

No

---

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	8 JAN 2021
Day 5	Yes	10 JAN 2021
Day 7	Yes	12 JAN 2021
Day 9	Yes	14 JAN 2021
Day 14	Yes	19 JAN 2021
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

---

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	06 JAN 2021
Time of assessment ( <i>00:00-23:59</i> )	09:00 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 09:00
Height ( <i>xxx.x</i> )	ND - Not Done
Weight ( <i>xxx.x</i> )	ND - Not Done
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	83 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

06 JAN 2021

---

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

---

US3342127

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

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

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

06 JAN 2021

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

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 29 JAN 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3342127

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

Date of updated informed consent (*dd MMM yyyy*) 29 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes   
No

Under what version of the Protocol was the Participant unblinded? Amendment 5   
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 29 JAN 2021

Participant randomization assignment mRNA-1273   
Placebo

Actual Dose 1 mRNA-1273   
Placebo   
Not Administered

Actual Dose 2 mRNA-1273   
Placebo   
Not Administered

Will participant receive mRNA-1273? Yes   
No

Placebo Only Flag \_\_\_\_\_

Continuing with mRNA-1273 \_\_\_\_\_

US3342127

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 29 JAN 2021

---

Collection time (*00:00-23:59*) 09:50 (24 HR)

---

Collection date and time (derived) 29 JAN 2021 09:50

---

US3342127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Mar 2021 15:14:12

Generated On: 09 Jun 2021 17:08:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 29 JAN 2021

---

Collection time (*00:00 - 23:59*) 09:51

---

Collection Date and Time (derived) 29 JAN 2021 09:51

---

US3342127

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:34:52

Generated On: 09 Jun 2021 17:08:04

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

AEID	
Adverse event	SYNCOPE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 OCT 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"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

AEID

Adverse event

ORTHOSTATIC HYPOTENSION

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

08 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

09 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

AEID	
Adverse event	VIRAL URI
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)	30 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

AEID USA-US203-2021-MRNA-1273-P30  
1000012

Adverse event WORSENING OF CONGESTIVE  
HEART FAILURE

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 1 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 06 MAR 2021

Hospital Discharge Date (dd MMM yyyy) 22 MAR 2021

Admitted to ICU? Yes   
No   
Unknown

Number of Days in ICU

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US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

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  False

Concomitant Medication  True

Concomitant Procedure  True

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

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

---

PENDING MEDICAL RECORDS,  
PATIENT REPORTS  
NONCOMPLIANCE WITH  
CONGESTIVE HEART FAILURE  
MEDICATION REGIMEN LED TO  
PLEURAL EFFUSION.  
HOSPITALIZED. TESTED FOR  
SARS-COV-2: NEGATIVE. WILL  
PROVIDE FURTHER DETAILS  
ONCE MEDICAL RECORDS  
RECEIVED.

CALLED PATIENT 01APRIL2021  
TO GET MORE INFORMATION  
ABOUT SAE. PATIENT REPORTS  
THAT HE WAS ADMITTED TO  
HOSPITAL 06MAR2021 DUE TO  
SHORTNESS OF  
BREATH/DYSPNEA ON  
EXERTION AND DISCOVERED  
TO HAVE A LARGE PLEURAL  
EFFUSION. THORACENTESIS  
PERFORMED 06MAR2021 AND  
CYTOLOGY NEGATIVE AND  
WITH FURTHER STUDIES,  
SUPPORTING A DIAGNOSIS OF  
CHF AND STARTED LIPITOR (80  
MG QD) AND CARVEDILOL (6.25  
MG BID). STILL AWAITING  
MEDICAL RECORDS, WILL  
UPDATE ONCE RECEIVED.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

AEID USA-US203-2021-MRNA-1273-P30  
1000015

Adverse event PULMONARY EMBOLISM  
RIGHT LUNG

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 11 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening True

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 16 APR 2021

Hospital Discharge Date (dd MMM yyyy) 18 APR 2021

Admitted to ICU? Yes   
No   
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

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  False

Concomitant Medication  True

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 \_\_\_\_\_

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

---

SOB ONSET 11APR2021  
WORSENING OVER TIME. PT  
REPORTS GOING TO THE  
HOSPITAL AT 0630 ON  
16APR2021. PT STATES HE HAD  
CHEST XRAY, CT SCAN, U/S OF  
HEART, LAB WORK AND COVID  
TEST (PENDING RESULTS). PT  
WAS ADMITTED TO THE  
HOSPITAL DUE TO  
PULMONARY EMBOLISM IN  
RIGHT LUNG. PT WAS STARTED  
ON 2 NEW  
MEDICATIONS-SPIRONOLACTO  
NE (UNKNOWN DOSAGE) AND  
LOVENOX (UNKNOWN  
DOSAGE). RELEASE OF  
MEDICAL RECORDS SENT.  
PENDING RECORDS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Mar 2021 15:14:11

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---

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

Yes

No

---

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

---

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:34:57

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Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

---

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 2015

---

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

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

Name of Medication BUSPIRONE HYDROCHLORIDE

Prophylaxis Yes   
No

Indication ANXIETY

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)

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2010

---

Start date completely unknown False

---

Ongoing? Yes   
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

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:34:57

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Name of Medication LORATIDINE

Prophylaxis Yes   
No

Indication SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

- 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) UN UNK 2015

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

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 16:34:57

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Name of Medication FLUTICASONE

Prophylaxis Yes   
No

Indication SEASONAL ALLERGIES

Dose per administration 50

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify MCG

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

---

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 JAN 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) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) \_\_\_\_\_ 802   
803   
804

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 16:34:57

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Name of Medication ESCITALOPRAM

Prophylaxis Yes   
No

Indication DEPRESSION

Dose per administration 5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 16:34:57

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---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2015

---

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

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication INJECTION SITE PAIN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 16:34:57

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---

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 21 AUG 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 23 AUG 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

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication HEADACHE

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 16:34:57

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---

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 22 SEP 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 22 SEP 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

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication VIRAL URI AE

Dose per administration 325

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

---

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*) 30 DEC 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 31 DEC 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

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

Name of Medication LIPITOR

Prophylaxis Yes   
No

Indication WORSENING OF CONGESTIVE  
HEART FAILURE SAE

Dose per administration 80

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

---

	Intraocular	<input type="radio"/>
	Intramuscular	<input 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) 22 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

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

Name of Medication CARVEDILOL

Prophylaxis Yes   
No

Indication WORSENING OF CONGESTIVE  
HEART FAILURE SAE

Dose per administration 6.25

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

---

Intraocular	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy) 22 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) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

Name of Medication PNEUMOVAX 23

Prophylaxis Yes   
No

Indication PNEUMONIA 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)

446 of 2773

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

---

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*) 12 APR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 12 APR 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

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

Name of Medication SPIRONOLACTONE

Prophylaxis Yes   
No

Indication PULMONARY EMBOLISM  
RIGHT LUNG SAE

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

448 of 2773

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

---

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy) 16 APR 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) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

Name of Medication LOVENOX

Prophylaxis Yes   
No

Indication PULMONARY EMBOLISM  
RIGHT LUNG SAE

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

---

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 16 APR 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) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3342127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 15:31:17

Generated On: 09 Jun 2021 17:08:04

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3342127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 15:31:17

Generated On: 09 Jun 2021 17:08:04

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
06 MAR 2021	THORACENTESIS	Adverse Event	

US3342127

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:08:04

---

Date of dosing discontinuation (dd MMM yyyy)

---

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by  
participant (specify)

Due to SARS-COV-2

Other

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

---

US3342127

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:08:04

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

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 15:31:17

Generated On: 09 Jun 2021 17:08:04

SAEID	USA-US203-2021-MRNA-1273-P30 1000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 15:31:17

Generated On: 09 Jun 2021 17:08:04

SAEID	USA-US203-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	11/MAR/2021 11:55
<b>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.</b>	True

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 15:31:17

Generated On: 09 Jun 2021 17:08:04

SAEID	USA-US203-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	02/APR/2021 12:26
<b>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.</b>	<input checked="" type="checkbox"/> True

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

SAEID	USA-US203-2021-MRNA-1273-P30 1000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

SAEID	USA-US203-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
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)	19/APR/2021 12:04
<b>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.</b>	<input checked="" type="checkbox"/> True

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 16:34:57

Generated On: 09 Jun 2021 17:08:04

SAEID	USA-US203-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
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)	20/APR/2021 15:02
<b>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.</b>	<input checked="" type="checkbox"/> True

Audit

US3342127 (Prod: Tekton Research- Austin)

US3342127

Form: Participant Creation

Generated On: 09 Jun 2021 17:08:04

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:53:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'US3342127'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:19:39

US3342127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:56:15
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:01

US3342127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:56:15
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:19:40

US3342127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:56:15
User entered 'Clinic (Clinic)'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:01

US3342127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'SCRN'	System	20 Aug 2020 16:53:01

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:19:41

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered '64'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'YEARS'	System	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '64'	System	20 Aug 2020 16:53:24

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered 'Male (M)'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered 'l'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:04

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:37
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:11

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:48
User entered '20 Aug 2020'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:24

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Aug 2020'	System	20 Aug 2020 16:53:24

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '2020'	System	20 Aug 2020 16:53:24

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:39:28
User closed query 'Subject signed ICF for Amendment 3 on 8/20/20. Please correct in EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:39:12
Query 'Subject signed ICF for Amendment 3 on 8/20/20. Please correct in EDC or clarify.' answered with 'patient signed Amendment 2 at the time of the visit we were using Amendment 2' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 22:15:42
User opened query 'Subject signed ICF for Amendment 3 on 8/20/20. Please correct in EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:01:21
DataPoint Un-verified.		29 Oct 2020 14:57:50
DataPoint Verified.		29 Oct 2020 14:57:48
User entered 'Amendment 2 (2)'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:24

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:48
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:24

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:48
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 16:53:24

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:48
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 16:53:24

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:48
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:24

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 14:57:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:19:40

US3342127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:04

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'I'	System	20 Aug 2020 16:53:29

US3342127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:01:28
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 16:53:29

US3342127

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:08:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:01:36
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:09:17

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:13:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:13:27
Data point term sent to Coder	System	20 Aug 2020 17:12:25
User entered 'anxiety'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:33
	(b) (4)	
	(b) (4)	

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'un UNK 2010'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:33

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:33

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:33

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 17:11:33

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:33

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 2010'	System	20 Aug 2020 17:11:33

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '2010'	System	20 Aug 2020 17:11:33

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	20 Aug 2020 17:11:33

US3342127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	20 Aug 2020 17:11:33

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Cardiac arrhythmia - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:12
Data point term sent to Coder	System	29 Oct 2020 15:02:24
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:02:22
User closed query 'Per DM CLR: Please specify the type of arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 19:47:33
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Cardiac arrhythmia - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 13:32:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 13:32:54
Data point term sent to Coder	System	29 Sep 2020 22:52:48
Coding entries removed.	Eileen Euperio (b) (4)	29 Sep 2020 22:51:49
User entered 'HEART ARRHYTHMIA (TYPE UNKNOWN)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	29 Sep 2020 22:51:49
Query 'Per DM CLR: Please specify the type of arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'TYPE UNKNOWN, WILL UPDATE' (Site from DM).	Eileen Euperio (b) (4)	29 Sep 2020 22:51:41

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the type of arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:41:08
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Cardiac arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:13:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:13:27
Data point term sent to Coder	System	20 Aug 2020 17:12:26
User entered 'heart arrhythmia'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'un UNK 2010'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 2010'	System	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '2010'	System	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	20 Aug 2020 17:11:51

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as SOC: Vascular disorders, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:10
Data point term sent to Coder	System	29 Oct 2020 15:02:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:02:22
User coded data point as SOC: Vascular disorders, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:13:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:13:27
Data point term sent to Coder	System	20 Aug 2020 17:12:26
User entered 'deep vein thrombosis'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'un UNK 1988'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'un UNK 1988'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 1988'	System	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '1988'	System	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 1988'	System	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '1988'	System	20 Aug 2020 17:12:12

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:12
Data point term sent to Coder	System	29 Oct 2020 15:02:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:02:22
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:14:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:14:29
Data point term sent to Coder	System	20 Aug 2020 17:13:27
User entered 'depression'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'un UNK 2015'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 2015'	System	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '2015'	System	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	20 Aug 2020 17:12:27

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis B, LLT: Hepatitis B - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:12
Data point term sent to Coder	System	29 Oct 2020 15:02:23
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:02:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis B, LLT: Hepatitis B - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:14:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:14:31
Data point term sent to Coder	System	20 Aug 2020 17:13:28
User entered 'hepatitis b'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'un UNK 2006'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User closed query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 19:47:50
Query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' answered with 'PER PATIENT REPORT, RESOLEVD ON ITS OWN W/O TREATMENT OR MEDS. NOT A CHRONIC LIVER DISEASE' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:51:04
User opened query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:41:22
User entered 'un UNK 2006'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 2006'	System	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '2006'	System	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 2006'	System	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '2006'	System	20 Aug 2020 17:12:48

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:11
Data point term sent to Coder	System	29 Oct 2020 15:02:24
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:02:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:14:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:14:31
Data point term sent to Coder	System	20 Aug 2020 17:13:28
User entered 'seasonal allergies'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'un UNK 2000'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 2000'	System	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '2000'	System	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	20 Aug 2020 17:13:06

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Gun shot wound, LLT: Gun shot wound - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 04:24:11
Data point term sent to Coder	System	29 Oct 2020 15:02:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:02:22
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Gun shot wound, LLT: Gun shot wound - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:15:19
Data point term sent to Coder	System	20 Aug 2020 17:14:29
User entered 'gun shot wound'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'un UNK 1980'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered 'un UNK 1980'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:02:22
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 1980'	System	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '1980'	System	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 1980'	System	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '1980'	System	20 Aug 2020 17:13:32

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:18:30
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 13:11:03
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'per investigator, condition = mild & treatment consists of lifestyle changes; pt did NOT report any medications.' (Site from DM).	Olivia Hapanowicz (b) (4)	18 Mar 2021 16:52:46
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 13:43:56
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 20:24:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 20:24:02
Data point term sent to Coder System	System	10 Mar 2021 20:23:29
User entered 'Congestive heart failure'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:18:30
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'un UNK 2017'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:18:30
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:18:30
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:18:30
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:18:30
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'Jan 2017'	System	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '2017'	System	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered empty.	System	10 Mar 2021 20:22:35

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) Sherrie Lancaster (b) (4)	29 Oct 2020 15:06:21
User entered '20 Aug 2020'	(b) (4) Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered '11:09'	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '20 Aug 2020 11:09'	System	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered '182' cm	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07
DataPoint set to visible.	System	20 Aug 2020 16:53:29

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered '79.6' kg	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07
DataPoint set to visible.	System	20 Aug 2020 16:53:29

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
Amendment Manager: User entered '24.03091'	System	17 Sep 2020 00:16:13
User entered '24.0'	System	20 Aug 2020 17:03:07
DataPoint set to visible.	System	20 Aug 2020 16:53:29

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'kg/m2'	System	20 Aug 2020 17:03:07
DataPoint set to visible.	System	20 Aug 2020 16:53:29

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:47
User entered '98' F	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered empty; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:47
User entered 'Oral (Oral)'	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:47
User entered '50'	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'bpm'	System	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:47
User entered '16'	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'breaths/min'	System	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:47
User entered '127'	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'mmHg'	System	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:21
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:47
User entered '82'	Stefanie Mott (b) (4)	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'mmHg'	System	20 Aug 2020 17:03:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07

US3342127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07

US3342127

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:43
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:03:15

US3342127

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:06:43
User entered '20 Aug 2020'	Stefanie Mott (b) (4)	20 Aug 2020 17:03:15

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Manufacturing & Production Operations](#) with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered 'goes to >3 stores per week; rides public transport'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered '1'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered '0'	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:04
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 17:04:23

US3342127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:24
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 16:52:41

US3342127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:24
User entered '20 Aug 2020'	Stefanie Mott (b) (4)	20 Aug 2020 16:52:41

US3342127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:07:24
User entered 'Clinic (Clinic)'	Stefanie Mott (b) (4)	20 Aug 2020 16:52:41

US3342127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'VISIT1'	System	20 Aug 2020 16:52:41

US3342127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:04

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:08
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:54:54

US3342127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:04

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:08
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:54:08
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:54:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 16:54:54
User entered '106186' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:54:54

US3342127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:04

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:08
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:54:54

US3342127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:04

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)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:08
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:05:05

US3342127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:04

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)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:08
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:05:05

US3342127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:04

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:08
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:05:05

US3342127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:08
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:05:05

US3342127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:04

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:08
User entered 'No (N)'	Stefanie Mott (b) (4)	20 Aug 2020 17:05:05

US3342127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:04

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:45:57

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:18
User entered '182' cm	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:18
User entered '79.6' kg	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:18
User entered '182' cm	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:18
User entered '79.6' kg	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User accepted default value 'Pre-Dose (PREDOSE)'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '20 Aug 2020'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '11:09'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '20 Aug 2020 11:09'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '98' F	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered 'Oral (Oral)'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '50'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'bpm'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '16'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'breaths/min'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '127'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '82'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:18
User entered '182' cm	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:18
User entered '79.6' kg	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User accepted default value 'Post-Dose (POSTDOSE)'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '20 Aug 2020'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:54:05
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 min post dose assessment per protocol ' (Site from System).	Stefanie Mott (b) (4)	20 Aug 2020 18:07:34
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 18:07:08
User entered '12:50'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '20 Aug 2020 12:50'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '98.3' F	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered 'Oral (Oral)'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '58'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'bpm'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '14'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'breaths/min'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '146'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:43
User entered '97'	Stefanie Mott (b) (4)	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	20 Aug 2020 18:07:08

US3342127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:55
User entered 'No (N)' reason for change: Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:03
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:05:21

US3342127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:08:55
User entered empty; reason for change Data Entry Error	John Luna (b) (4)	24 Aug 2020 15:27:03
User entered '20 Aug 2020'	Stefanie Mott (b) (4)	20 Aug 2020 17:05:21

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:09:19
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:09:19
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

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 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:09:19
User entered empty.	Stefanie Mott (b) (4)	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:09:19
User entered '20 Aug 2020'	Stefanie Mott (b) (4)	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:09:19
User entered '12:19'	Stefanie Mott (b) (4)	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '20 Aug 2020 12:19'	System	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:09:19
User entered 'Left Arm (LEFT ARM)'	Stefanie Mott (b) (4)	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:09:19
User entered 'ONCE'	System	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 17:37:51

US3342127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:10:15
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	24 Aug 2020 19:13:50

US3342127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:10:17
User entered '20 Aug 2020'	Andrew Bell (b) (4) (b) (4)	24 Aug 2020 19:13:50

US3342127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4)	29 Oct 2020 15:11:52
Query 'Per source, collection time was 11:55. Please correct in EDC or clarify.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:11:49
User opened query 'Per source, collection time was 11:55. Please correct in EDC or clarify.' (Site from CRA).	(b) (4)	29 Oct 2020 15:10:54
User entered '11:57'	Andrew Bell (b) (4)	24 Aug 2020 19:13:50
	(b) (4)	

US3342127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '20 Aug 2020 11:57'	System	24 Aug 2020 19:13:50

US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:02
User entered '20 Aug 2020'	Andrew Bell (b) (4) (b) (4)	24 Aug 2020 19:14:06

US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andrew Bell (b) (4) (b) (4)	24 Aug 2020 19:14:06

US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:02
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	24 Aug 2020 19:14:06

US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:02
User entered '11:59'	Andrew Bell (b) (4) (b) (4)	24 Aug 2020 19:14:06

US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '20 Aug 2020 11:59'	System	24 Aug 2020 19:14:06

US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andrew Bell (b) (4) (b) (4)	24 Aug 2020 19:14:06

US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:02
User entered 'No (N)'	Andrew Bell (b) (4) (b) (4)	24 Aug 2020 19:14:06

US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:02
User entered empty.	Andrew Bell (b) (4) (b) (4)	24 Aug 2020 19:14:06

US3342127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered empty.	System	24 Aug 2020 19:14:06

US3342127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:12:10
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:38:30

US3342127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '1'	System	20 Aug 2020 17:38:30

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:52:36', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '879fa3b9-3979-49e4-aaef-9bc6b5210242'	System	20 Aug 2020 17:53:10
User entered 'Yes (Y)'	System	20 Aug 2020 17:53:10

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:52:49', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '879fa3b9-3979-49e4-aaef-9bc6b5210242'	System	20 Aug 2020 17:53:10
User entered '98.3'	System	20 Aug 2020 17:53:10

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:52:57', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '879fa3b9-3979-49e4-aaef-9bc6b5210242'	System	20 Aug 2020 17:53:10
User entered 'No (N)'	System	20 Aug 2020 17:53:10

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:53:08', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '879fa3b9-3979-49e4-aaef-9bc6b5210242'	System	20 Aug 2020 17:53:10
User entered '20 Aug 2020 12:53'	System	20 Aug 2020 17:53:10

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '20 Aug 2020 12:39'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '20 Aug 2020 15:09'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:54:53', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'e8c04514-f9c0-4d66-b966-9e7decd83bf1'	System	20 Aug 2020 22:55:49
User entered 'Yes (Y)'	System	20 Aug 2020 22:55:49

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:55:13', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'e8c04514-f9c0-4d66-b966-9e7decd83bf1' User entered '98.6'	System	20 Aug 2020 22:55:49
	System	20 Aug 2020 22:55:49

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:55:23', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'e8c04514-f9c0-4d66-b966-9e7decd83bf1'	System	20 Aug 2020 22:55:49
User entered 'No (N)'	System	20 Aug 2020 22:55:49

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:55:45', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'e8c04514-f9c0-4d66-b966-9e7dec83bf1'	System	20 Aug 2020 22:55:49
User entered '20 Aug 2020 17:55'	System	20 Aug 2020 22:55:49

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '20 Aug 2020 16:04'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 2'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T20:42:49', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a1eb5b99-5d3d-427a-a22d-ed5c9b8c9911'	System	22 Aug 2020 01:43:30
User entered 'Yes (Y)'	System	22 Aug 2020 01:43:30

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T20:43:03', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a1eb5b99-5d3d-427a-a22d-ed5c9b8c9911'	System	22 Aug 2020 01:43:30
User entered '98.7'	System	22 Aug 2020 01:43:30

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T20:43:13', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a1eb5b99-5d3d-427a-a22d-ed5c9b8c9911'	System	22 Aug 2020 01:43:30
User entered 'No (N)'	System	22 Aug 2020 01:43:30

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T20:43:27', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a1eb5b99-5d3d-427a-a22d-ed5c9b8c9911'	System	22 Aug 2020 01:43:30
User entered '21 Aug 2020 20:43'	System	22 Aug 2020 01:43:30

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 3'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 4'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 5'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 6'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:33:55', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'cdfb8366-38dd-4e32-8373-b95bf919c744'	System	25 Aug 2020 17:34:23
User entered 'Yes (Y)'	System	25 Aug 2020 17:34:23

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:34:07', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'cdfb8366-38dd-4e32-8373-b95bf919c744'	System	25 Aug 2020 17:34:23
User entered '98.6'	System	25 Aug 2020 17:34:23

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:34:13', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'cdfb8366-38dd-4e32-8373-b95bf919c744'	System	25 Aug 2020 17:34:23
User entered 'No (N)'	System	25 Aug 2020 17:34:23

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:34:21', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'cdfb8366-38dd-4e32-8373-b95bf919c744'	System	25 Aug 2020 17:34:23
User entered '25 Aug 2020 12:34'	System	25 Aug 2020 17:34:23

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 7'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:49:03', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '998bcb94-ceb9-4e0f-9412-9cb157a5dff7'	System	27 Aug 2020 00:49:36
User entered 'Yes (Y)'	System	27 Aug 2020 00:49:36

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:49:16', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '998bcb94-ceb9-4e0f-9412-9cb157a5dff7'	System	27 Aug 2020 00:49:36
User entered '98.5'	System	27 Aug 2020 00:49:36

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:49:22', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '998bcb94-ceb9-4e0f-9412-9cb157a5dff7'	System	27 Aug 2020 00:49:36
User entered 'No (N)'	System	27 Aug 2020 00:49:36

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:49:29', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '998bcb94-ceb9-4e0f-9412-9cb157a5dff7'	System	27 Aug 2020 00:49:36
User entered '26 Aug 2020 19:49'	System	27 Aug 2020 00:49:36

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:53:45', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '40938e42-0944-4ec1-a06a-649e2be7c18d'	System	20 Aug 2020 17:54:25
User entered 'None (1)'	System	20 Aug 2020 17:54:25

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:53:52', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '40938e42-0944-4ec1-a06a-649e2be7c18d'	System	20 Aug 2020 17:54:25
User entered 'No (N)'	System	20 Aug 2020 17:54:25

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:53:59', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '40938e42-0944-4ec1-a06a-649e2be7c18d'	System	20 Aug 2020 17:54:25
User entered 'No (N)'	System	20 Aug 2020 17:54:25

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:54:12', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '40938e42-0944-4ec1-a06a-649e2be7c18d'	System	20 Aug 2020 17:54:25
User entered 'None (1)'	System	20 Aug 2020 17:54:25

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:54:20', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '40938e42-0944-4ec1-a06a-649e2be7c18d' User entered '20 Aug 2020 12:54'	System	20 Aug 2020 17:54:25
	System	20 Aug 2020 17:54:25

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '20 Aug 2020 12:39'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '20 Aug 2020 15:09'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:56:06', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'bfac9be6-f892-4ca1-9dbb-eeclda6d03ac'	System	20 Aug 2020 22:57:15
User entered 'None (1)'	System	20 Aug 2020 22:57:15

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:56:18', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'bfac9be6-f892-4ca1-9dbb-ee1da6d03ac'	System	20 Aug 2020 22:57:15
User entered 'No (N)'	System	20 Aug 2020 22:57:15

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:56:25', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'bfac9be6-f892-4ca1-9dbb-ee1da6d03ac'	System	20 Aug 2020 22:57:15
User entered 'No (N)'	System	20 Aug 2020 22:57:15

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:56:46', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'bfac9be6-f892-4ca1-9dbb-eeclda6d03ac'	System	20 Aug 2020 22:57:15
User entered 'None (1)'	System	20 Aug 2020 22:57:15

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:57:09', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'bfac9be6-f892-4ca1-9dbb-ee1da6d03ac'	System	20 Aug 2020 22:57:15
User entered '20 Aug 2020 17:57'	System	20 Aug 2020 22:57:15

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '20 Aug 2020 16:04'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 2'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:02:17', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '0297acb5-6349-4ff1-bdba-31b036919dc5'	System	22 Aug 2020 03:03:24
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 03:03:24

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:02:25', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '0297acb5-6349-4ff1-bdba-31b036919dc5'	System	22 Aug 2020 03:03:24
User entered 'No (N)'	System	22 Aug 2020 03:03:24

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:02:32', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '0297acb5-6349-4ff1-bdba-31b036919dc5'	System	22 Aug 2020 03:03:24
User entered 'Yes (Y)'	System	22 Aug 2020 03:03:24

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:02:58', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '0297acb5-6349-4ff1-bdba-31b036919dc5'	System	22 Aug 2020 03:03:24
User entered '3'	System	22 Aug 2020 03:03:24

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:03:05', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '0297acb5-6349-4ff1-bdba-31b036919dc5'	System	22 Aug 2020 03:03:24
User entered 'None (1)'	System	22 Aug 2020 03:03:24

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:03:20', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '0297acb5-6349-4ff1-bdba-31b036919dc5' User entered '21 Aug 2020 22:03'	System	22 Aug 2020 03:03:24
	System	22 Aug 2020 03:03:24

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 3'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 4'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 5'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 6'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:34:29', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fe76d525-80b9-4e91-a3ab-d00226a06c28'	System	25 Aug 2020 17:34:50
User entered 'None (1)'	System	25 Aug 2020 17:34:50

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:34:33', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fe76d525-80b9-4e91-a3ab-d00226a06c28'	System	25 Aug 2020 17:34:50
User entered 'No (N)'	System	25 Aug 2020 17:34:50

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:34:37', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fe76d525-80b9-4e91-a3ab-d00226a06c28'	System	25 Aug 2020 17:34:50
User entered 'No (N)'	System	25 Aug 2020 17:34:50

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:34:43', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fe76d525-80b9-4e91-a3ab-d00226a06c28'	System	25 Aug 2020 17:34:50
User entered 'None (1)'	System	25 Aug 2020 17:34:50

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:34:46', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fe76d525-80b9-4e91-a3ab-d00226a06c28'	System	25 Aug 2020 17:34:50
User entered '25 Aug 2020 12:34'	System	25 Aug 2020 17:34:50

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 7'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:49:41', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '416bd7b4-d302-4938-a4f3-a7e7c0014473'	System	27 Aug 2020 00:50:10
User entered 'None (1)'	System	27 Aug 2020 00:50:10

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:49:46', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '416bd7b4-d302-4938-a4f3-a7e7c0014473'	System	27 Aug 2020 00:50:10
User entered 'No (N)'	System	27 Aug 2020 00:50:10

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:49:50', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '416bd7b4-d302-4938-a4f3-a7e7c0014473'	System	27 Aug 2020 00:50:10
User entered 'No (N)'	System	27 Aug 2020 00:50:10

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:49:57', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '416bd7b4-d302-4938-a4f3-a7e7c0014473'	System	27 Aug 2020 00:50:10
User entered 'None (1)'	System	27 Aug 2020 00:50:10

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:50:04', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '416bd7b4-d302-4938-a4f3-a7e7c0014473'	System	27 Aug 2020 00:50:10
User entered '26 Aug 2020 19:50'	System	27 Aug 2020 00:50:10

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:54:39', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '96256c03-42e4-429b-8065-a4a85e2afd01'	System	20 Aug 2020 17:55:27
User entered 'None (0)'	System	20 Aug 2020 17:55:27

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:54:43', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '96256c03-42e4-429b-8065-a4a85e2afd01'	System	20 Aug 2020 17:55:27
User entered 'None (0)'	System	20 Aug 2020 17:55:27

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:54:48', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '96256c03-42e4-429b-8065-a4a85e2afd01'	System	20 Aug 2020 17:55:27
User entered 'None (0)'	System	20 Aug 2020 17:55:27

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:54:53', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '96256c03-42e4-429b-8065-a4a85e2afd01'	System	20 Aug 2020 17:55:27
User entered 'None (0)'	System	20 Aug 2020 17:55:27

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:54:57', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '96256c03-42e4-429b-8065-a4a85e2afd01'	System	20 Aug 2020 17:55:27
User entered 'None (0)'	System	20 Aug 2020 17:55:27

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:55:01', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '96256c03-42e4-429b-8065-a4a85e2afd01'	System	20 Aug 2020 17:55:27
User entered 'None (0)'	System	20 Aug 2020 17:55:27

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:55:16', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '96256c03-42e4-429b-8065-a4a85e2afd01'	System	20 Aug 2020 17:55:27
User entered 'No (N)'	System	20 Aug 2020 17:55:27

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T12:55:23', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '96256c03-42e4-429b-8065-a4a85e2afd01'	System	20 Aug 2020 17:55:27
User entered '20 Aug 2020 12:55'	System	20 Aug 2020 17:55:27

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '20 Aug 2020 12:39'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '20 Aug 2020 15:09'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:57:36', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a2209224-9d47-4c4a-876e-9bc09c314a0d'	System	20 Aug 2020 22:58:39
User entered 'None (0)'	System	20 Aug 2020 22:58:39

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:57:42', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a2209224-9d47-4c4a-876e-9bc09c314a0d'	System	20 Aug 2020 22:58:39
User entered 'None (0)'	System	20 Aug 2020 22:58:39

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:57:49', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a2209224-9d47-4c4a-876e-9bc09c314a0d'	System	20 Aug 2020 22:58:39
User entered 'None (0)'	System	20 Aug 2020 22:58:39

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:57:59', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a2209224-9d47-4c4a-876e-9bc09c314a0d'	System	20 Aug 2020 22:58:39
User entered 'None (0)'	System	20 Aug 2020 22:58:39

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:58:03', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a2209224-9d47-4c4a-876e-9bc09c314a0d'	System	20 Aug 2020 22:58:39
User entered 'None (0)'	System	20 Aug 2020 22:58:39

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:58:16', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a2209224-9d47-4c4a-876e-9bc09c314a0d'	System	20 Aug 2020 22:58:39
User entered 'None (0)'	System	20 Aug 2020 22:58:39

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:58:25', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a2209224-9d47-4c4a-876e-9bc09c314a0d'	System	20 Aug 2020 22:58:39
User entered 'No (N)'	System	20 Aug 2020 22:58:39

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-20T17:58:34', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'a2209224-9d47-4c4a-876e-9bc09c314a0d'	System	20 Aug 2020 22:58:39
User entered '20 Aug 2020 17:58'	System	20 Aug 2020 22:58:39

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '20 Aug 2020 16:04'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 2'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:03:29', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '43f0e227-f017-44ef-8a76-3158c0a055bc'	System	22 Aug 2020 03:04:19
User entered 'None (0)'	System	22 Aug 2020 03:04:19

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:03:40', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '43f0e227-f017-44ef-8a76-3158c0a055bc'	System	22 Aug 2020 03:04:19
User entered 'None (0)'	System	22 Aug 2020 03:04:19

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:03:47', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '43f0e227-f017-44ef-8a76-3158c0a055bc'	System	22 Aug 2020 03:04:19
User entered 'None (0)'	System	22 Aug 2020 03:04:19

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:03:52', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '43f0e227-f017-44ef-8a76-3158c0a055bc'	System	22 Aug 2020 03:04:19
User entered 'None (0)'	System	22 Aug 2020 03:04:19

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:03:57', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '43f0e227-f017-44ef-8a76-3158c0a055bc'	System	22 Aug 2020 03:04:19
User entered 'None (0)'	System	22 Aug 2020 03:04:19

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:04:03', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '43f0e227-f017-44ef-8a76-3158c0a055bc'	System	22 Aug 2020 03:04:19
User entered 'None (0)'	System	22 Aug 2020 03:04:19

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:04:11', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '43f0e227-f017-44ef-8a76-3158c0a055bc'	System	22 Aug 2020 03:04:19
User entered 'No (N)'	System	22 Aug 2020 03:04:19

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-21T22:04:16', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '43f0e227-f017-44ef-8a76-3158c0a055bc'	System	22 Aug 2020 03:04:19
User entered '21 Aug 2020 22:04'	System	22 Aug 2020 03:04:19

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 3'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 4'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 5'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 6'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:34:56', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '231ddbc9-6b1c-4a17-adf1-00ffb88798af' User entered 'None (0)'	System	25 Aug 2020 17:35:37
	System	25 Aug 2020 17:35:37

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:35:01', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '231ddbc9-6b1c-4a17-adf1-00ffb88798af' User entered 'None (0)'	System	25 Aug 2020 17:35:37
	System	25 Aug 2020 17:35:37

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:35:07', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '231ddbc9-6b1c-4a17-adf1-00ffb88798af' User entered 'None (0)'	System	25 Aug 2020 17:35:37
	System	25 Aug 2020 17:35:37

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:35:13', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '231ddbc9-6b1c-4a17-adf1-00ffb88798af' User entered 'None (0)'	System	25 Aug 2020 17:35:37
	System	25 Aug 2020 17:35:37

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:35:18', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '231ddbc9-6b1c-4a17-adf1-00ffb88798af' User entered 'None (0)'	System	25 Aug 2020 17:35:37
	System	25 Aug 2020 17:35:37

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:35:22', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '231ddbc9-6b1c-4a17-adf1-00ffb88798af'	System	25 Aug 2020 17:35:37
User entered 'None (0)'	System	25 Aug 2020 17:35:37

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:35:28', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '231ddbc9-6b1c-4a17-adf1-00ffb88798af' User entered 'No (N)'	System	25 Aug 2020 17:35:37
	System	25 Aug 2020 17:35:37

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-25T12:35:34', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '231ddbc9-6b1c-4a17-adf1-00ffb88798af'	System	25 Aug 2020 17:35:37
User entered '25 Aug 2020 12:35'	System	25 Aug 2020 17:35:37

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 7'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:50:27', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c5540aae-9d74-4d34-b08b-08d2e782c2ca'	System	27 Aug 2020 00:51:14
User entered 'None (0)'	System	27 Aug 2020 00:51:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:50:31', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c5540aae-9d74-4d34-b08b-08d2e782c2ca'	System	27 Aug 2020 00:51:14
User entered 'None (0)'	System	27 Aug 2020 00:51:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:50:37', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c5540aae-9d74-4d34-b08b-08d2e782c2ca'	System	27 Aug 2020 00:51:14
User entered 'None (0)'	System	27 Aug 2020 00:51:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:50:43', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c5540aae-9d74-4d34-b08b-08d2e782c2ca'	System	27 Aug 2020 00:51:14
User entered 'None (0)'	System	27 Aug 2020 00:51:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:50:48', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c5540aae-9d74-4d34-b08b-08d2e782c2ca'	System	27 Aug 2020 00:51:14
User entered 'None (0)'	System	27 Aug 2020 00:51:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:50:51', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c5540aae-9d74-4d34-b08b-08d2e782c2ca'	System	27 Aug 2020 00:51:14
User entered 'None (0)'	System	27 Aug 2020 00:51:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:50:57', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c5540aae-9d74-4d34-b08b-08d2e782c2ca'	System	27 Aug 2020 00:51:14
User entered 'No (N)'	System	27 Aug 2020 00:51:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-08-26T19:51:08', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c5540aae-9d74-4d34-b08b-08d2e782c2ca'	System	27 Aug 2020 00:51:14
User entered '26 Aug 2020 19:51'	System	27 Aug 2020 00:51:14

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:37:51

US3342127

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:08
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	27 Aug 2020 20:28:56

US3342127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:08
User entered '27 Aug 2020'	Ethan Shotton (b) (4) (b) (4)	27 Aug 2020 20:28:56

US3342127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:08
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	27 Aug 2020 20:28:56

US3342127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:08
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Aug 2020 20:28:56

US3342127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:22
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	27 Aug 2020 20:28:59

US3342127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'I'	System	27 Aug 2020 20:28:59

US3342127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:45
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	04 Sep 2020 14:28:44

US3342127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:45
User entered '4 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	04 Sep 2020 14:28:44

US3342127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:45
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	04 Sep 2020 14:28:44

US3342127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:45
User entered empty.	Ethan Shotton (b) (4) (b) (4)	04 Sep 2020 14:28:44

US3342127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:13:59
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	04 Sep 2020 14:28:47

US3342127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'I'	System	04 Sep 2020 14:28:47

US3342127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:17:07
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	10 Sep 2020 16:36:27

US3342127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:17:07
User entered '10 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	10 Sep 2020 16:36:27

US3342127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:17:07
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	10 Sep 2020 16:36:27

US3342127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:17:07
User entered empty.	Ethan Shotton (b) (4) (b) (4)	10 Sep 2020 16:36:27

US3342127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:17:14
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	10 Sep 2020 16:36:31

US3342127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '1'	System	10 Sep 2020 16:36:31

US3342127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:21:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 16:58:36

US3342127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:21:24
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 16:58:36

US3342127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:21:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 16:58:36

US3342127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'VISIT2'	System	21 Sep 2020 16:58:36

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:26:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:26:16
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:40:01
User closed query 'Source states 11:05. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:39:59
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
Query 'Source states 11:05. Please review and reconcile. ' answered with 'Updated per source.' (Site from CRA).	Darrell O'Brien (b) (4)	06 Jan 2021 01:39:04
User entered '11:05' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 01:38:48
User opened query 'Source states 11:05. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 19:25:50
User entered '10:59'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '21 Sep 2020 11:05'	System	06 Jan 2021 01:38:48
User entered '21 Sep 2020 10:59'	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:26:23
User entered '98.6' F	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:26:27
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:26:29
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:27:47
User entered '71'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'bpm'	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:27:57
User entered '14'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'breaths/min'	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:28:00
User entered '129'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:28:02
User entered '70'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:28:48
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:45:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 17:45:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:45:58
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 16:59:27
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:28:50
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:45:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:28:52
User entered '12:43' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:45:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '21 Sep 2020 12:43'	System	21 Sep 2020 17:45:58
User entered empty.	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:28:54
User entered '97.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:45:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:28:55
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:45:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:28:57
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:28:58
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:45:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'bpm'	System	21 Sep 2020 17:45:58
User entered empty.	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:29:00
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:45:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'breaths/min'	System	21 Sep 2020 17:45:58
User entered empty.	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:29:01
User entered '151' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:45:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	21 Sep 2020 17:45:58
User entered empty.	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:29:02
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:45:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	21 Sep 2020 17:45:58
User entered empty.	System	21 Sep 2020 16:59:27

US3342127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:29:13
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 16:59:35

US3342127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:29:13
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:59:35

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:29:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:29:43
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

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 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:30:21
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:30:21
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:30:21
User entered '12:12'	(b) (4), (b) (6)	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '21 Sep 2020 12:12'	System	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:30:21
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 19:30:21
User entered 'ONCE'	System	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 17:15:56

US3342127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:27
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:28

US3342127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:27
User entered '21 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:28

US3342127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:27
User entered '11:53'	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:28

US3342127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '21 Sep 2020 11:53'	System	23 Sep 2020 16:54:28

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:34
User entered '21 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:50

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:50

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:34
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:50

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:34
User entered '11:55'	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:50

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '21 Sep 2020 11:55'	System	23 Sep 2020 16:54:50

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:50

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:34
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:50

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:34
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	23 Sep 2020 16:54:50

US3342127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered empty.	System	23 Sep 2020 16:54:50

US3342127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:32:39
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	25 Sep 2020 22:36:42

US3342127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '1'	System	25 Sep 2020 22:36:42

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:49:19', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '2339ef90-fd02-4c97-818c-bd7af83da3fd'	System	21 Sep 2020 17:49:54
User entered 'Yes (Y)'	System	21 Sep 2020 17:49:54

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:49:33', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '2339ef90-fd02-4c97-818c-bd7af83da3fd' User entered '97.1'	System	21 Sep 2020 17:49:54
	System	21 Sep 2020 17:49:54

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:49:41', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '2339ef90-fd02-4c97-818c-bd7af83da3fd'	System	21 Sep 2020 17:49:54
User entered 'No (N)'	System	21 Sep 2020 17:49:54

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:49:50', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '2339ef90-fd02-4c97-818c-bd7af83da3fd'	System	21 Sep 2020 17:49:54
User entered '21 Sep 2020 12:49'	System	21 Sep 2020 17:49:54

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Sep 2020 12:32'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Sep 2020 15:02'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:36:58', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '9ef0a057-6890-4b79-ad2f-ad488695e5f9'	System	21 Sep 2020 21:37:57
User entered 'Yes (Y)'	System	21 Sep 2020 21:37:57

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:37:40', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '9ef0a057-6890-4b79-ad2f-ad488695e5f9' User entered '97.5'	System	21 Sep 2020 21:37:57
	System	21 Sep 2020 21:37:57

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:37:47', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '9ef0a057-6890-4b79-ad2f-ad488695e5f9'	System	21 Sep 2020 21:37:57
User entered 'No (N)'	System	21 Sep 2020 21:37:57

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:37:53', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '9ef0a057-6890-4b79-ad2f-ad488695e5f9'	System	21 Sep 2020 21:37:57
User entered '21 Sep 2020 16:37'	System	21 Sep 2020 21:37:57

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Sep 2020 15:57'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 2'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:18:32', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'b7af3609-bcf5-4700-be59-fcd56d3cb342'	System	23 Sep 2020 00:19:24
User entered 'Yes (Y)'	System	23 Sep 2020 00:19:24

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:18:42', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'b7af3609-bcf5-4700-be59-fcd56d3cb342'	System	23 Sep 2020 00:19:24
User entered '99.4'	System	23 Sep 2020 00:19:24

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:18:54', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'b7af3609-bcf5-4700-be59-fcd56d3cb342'	System	23 Sep 2020 00:19:24
User entered 'Yes (Y)'	System	23 Sep 2020 00:19:24

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
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 'aspirin to be added to conmeds' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 12:20:31
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.'	Eileen Euperio (b) (4)	29 Sep 2020 22:49:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:19:12', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'b7af3609-bcf5-4700-be59-fcd56d3cb342'	(b) (4)	
User entered '1'	System	23 Sep 2020 00:19:24
	System	23 Sep 2020 00:19:24
	System	23 Sep 2020 00:19:24

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:19:12', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'b7af3609-bcf5-4700-be59-fcd56d3cb342'	System	23 Sep 2020 00:19:24
User entered '0'	System	23 Sep 2020 00:19:24

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:19:19', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'b7af3609-bcf5-4700-be59-fcd56d3cb342'	System	23 Sep 2020 00:19:24
User entered '22 Sep 2020 19:19'	System	23 Sep 2020 00:19:24

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 3'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 4'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:20:48', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '916e486e-f654-4abe-a500-1864f37cbd46'	System	25 Sep 2020 01:23:53
User entered 'Yes (Y)'	System	25 Sep 2020 01:23:53

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:23:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '916e486e-f654-4abe-a500-1864f37cbd46'	System	25 Sep 2020 01:23:53
User entered '98.7'	System	25 Sep 2020 01:23:53

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:23:45', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '916e486e-f654-4abe-a500-1864f37cbd46'	System	25 Sep 2020 01:23:53
User entered 'No (N)'	System	25 Sep 2020 01:23:53

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:23:49', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '916e486e-f654-4abe-a500-1864f37cbd46'	System	25 Sep 2020 01:23:53
User entered '24 Sep 2020 20:23'	System	25 Sep 2020 01:23:53

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 5'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:04:57', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'cb2023a1-80d1-415c-b89f-cb29da131669'	System	25 Sep 2020 19:05:58
User entered 'Yes (Y)'	System	25 Sep 2020 19:05:58

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:05:43', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'cb2023a1-80d1-415c-b89f-cb29da131669'	System	25 Sep 2020 19:05:58
User entered '98.4'	System	25 Sep 2020 19:05:58

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:05:48', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'cb2023a1-80d1-415c-b89f-cb29da131669'	System	25 Sep 2020 19:05:58
User entered 'No (N)'	System	25 Sep 2020 19:05:58

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:05:53', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'cb2023a1-80d1-415c-b89f-cb29da131669'	System	25 Sep 2020 19:05:58
User entered '25 Sep 2020 14:05'	System	25 Sep 2020 19:05:58

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 6'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:05:27', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '91554358-62a1-4698-adc0-958c488e249b'	System	26 Sep 2020 20:07:19
User entered 'Yes (Y)'	System	26 Sep 2020 20:07:19

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:05:44', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '91554358-62a1-4698-adc0-958c488e249b' User entered '98.4'	System	26 Sep 2020 20:07:19
	System	26 Sep 2020 20:07:19

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:05:50', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '91554358-62a1-4698-adc0-958c488e249b'	System	26 Sep 2020 20:07:19
User entered 'No (N)'	System	26 Sep 2020 20:07:19

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:07:12', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '91554358-62a1-4698-adc0-958c488e249b'	System	26 Sep 2020 20:07:19
User entered '26 Sep 2020 15:07'	System	26 Sep 2020 20:07:19

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 7'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:50:05', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'dd0b1177-3c28-400b-8d43-0a419b3865cd'	System	21 Sep 2020 17:50:48
User entered 'None (1)'	System	21 Sep 2020 17:50:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:50:18', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'dd0b1177-3c28-400b-8d43-0a419b3865cd'	System	21 Sep 2020 17:50:48
User entered 'No (N)'	System	21 Sep 2020 17:50:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:50:25', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'dd0b1177-3c28-400b-8d43-0a419b3865cd'	System	21 Sep 2020 17:50:48
User entered 'No (N)'	System	21 Sep 2020 17:50:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:50:33', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'dd0b1177-3c28-400b-8d43-0a419b3865cd'	System	21 Sep 2020 17:50:48
User entered 'None (1)'	System	21 Sep 2020 17:50:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:50:43', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'dd0b1177-3c28-400b-8d43-0a419b3865cd'	System	21 Sep 2020 17:50:48
User entered '21 Sep 2020 12:50'	System	21 Sep 2020 17:50:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Sep 2020 12:32'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Sep 2020 15:02'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:38:08', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5a960a84-1577-4b67-888d-542e79797943'	System	21 Sep 2020 21:38:40
User entered 'None (1)'	System	21 Sep 2020 21:38:40

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:38:16', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5a960a84-1577-4b67-888d-542e79797943'	System	21 Sep 2020 21:38:40
User entered 'No (N)'	System	21 Sep 2020 21:38:40

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:38:25', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5a960a84-1577-4b67-888d-542e79797943'	System	21 Sep 2020 21:38:40
User entered 'No (N)'	System	21 Sep 2020 21:38:40

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:38:34', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5a960a84-1577-4b67-888d-542e79797943'	System	21 Sep 2020 21:38:40
User entered 'None (1)'	System	21 Sep 2020 21:38:40

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:38:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5a960a84-1577-4b67-888d-542e79797943'	System	21 Sep 2020 21:38:40
User entered '21 Sep 2020 16:38'	System	21 Sep 2020 21:38:40

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Sep 2020 15:57'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 2'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:36:02
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'pt answered this in regards to interferes with activity. did not take con med due to pain at injection site ' (Site from DM).	Stefanie Mott (b) (4)	23 Feb 2021 16:04:17
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 04:58:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:19:56', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd6b27f5a-30fd-4e21-804f-5c3d3f8a13a0'	System	23 Sep 2020 00:22:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	23 Sep 2020 00:22:09

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:20:01', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd6b27f5a-30fd-4e21-804f-5c3d3f8a13a0'	System	23 Sep 2020 00:22:09
User entered 'Yes (Y)'	System	23 Sep 2020 00:22:09

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:21:35', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd6b27f5a-30fd-4e21-804f-5c3d3f8a13a0'	System	23 Sep 2020 00:22:09
User entered '3'	System	23 Sep 2020 00:22:09

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:21:41', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd6b27f5a-30fd-4e21-804f-5c3d3f8a13a0'	System	23 Sep 2020 00:22:09
User entered 'Yes (Y)'	System	23 Sep 2020 00:22:09

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:21:54', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd6b27f5a-30fd-4e21-804f-5c3d3f8a13a0'	System	23 Sep 2020 00:22:09
User entered '3'	System	23 Sep 2020 00:22:09

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:22:01', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd6b27f5a-30fd-4e21-804f-5c3d3f8a13a0'	System	23 Sep 2020 00:22:09
User entered 'None (1)'	System	23 Sep 2020 00:22:09

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:22:05', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd6b27f5a-30fd-4e21-804f-5c3d3f8a13a0'	System	23 Sep 2020 00:22:09
User entered '22 Sep 2020 19:22'	System	23 Sep 2020 00:22:09

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 3'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 4'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:04', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '04f96820-1181-41aa-a8e1-17cb8e91ae6c'	System	25 Sep 2020 01:24:35
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 01:24:35

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:09', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '04f96820-1181-41aa-a8e1-17cb8e91ae6c'	System	25 Sep 2020 01:24:35
User entered 'No (N)'	System	25 Sep 2020 01:24:35

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:20', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '04f96820-1181-41aa-a8e1-17cb8e91ae6c'	System	25 Sep 2020 01:24:35
User entered 'No (N)'	System	25 Sep 2020 01:24:35

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:24', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '04f96820-1181-41aa-a8e1-17cb8e91ae6c'	System	25 Sep 2020 01:24:35
User entered 'None (1)'	System	25 Sep 2020 01:24:35

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:28', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '04f96820-1181-41aa-a8e1-17cb8e91ae6c'	System	25 Sep 2020 01:24:35
User entered '24 Sep 2020 20:24'	System	25 Sep 2020 01:24:35

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 5'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:06:06', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '483ddafd-035f-4464-8d4a-3bca179cd258'	System	25 Sep 2020 19:07:57
User entered 'None (1)'	System	25 Sep 2020 19:07:57

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:06:12', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '483ddafd-035f-4464-8d4a-3bca179cd258'	System	25 Sep 2020 19:07:57
User entered 'No (N)'	System	25 Sep 2020 19:07:57

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:06:27', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '483ddafd-035f-4464-8d4a-3bca179cd258'	System	25 Sep 2020 19:07:57
User entered 'No (N)'	System	25 Sep 2020 19:07:57

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:07:48', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '483ddafd-035f-4464-8d4a-3bca179cd258'	System	25 Sep 2020 19:07:57
User entered 'None (1)'	System	25 Sep 2020 19:07:57

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:07:53', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '483ddafd-035f-4464-8d4a-3bca179cd258'	System	25 Sep 2020 19:07:57
User entered '25 Sep 2020 14:07'	System	25 Sep 2020 19:07:57

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 6'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:07:20', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3b368d4f-d41f-4eb1-a62c-f879ad6b56df'	System	26 Sep 2020 20:07:48
User entered 'None (1)'	System	26 Sep 2020 20:07:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:07:25', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3b368d4f-d41f-4eb1-a62c-f879ad6b56df'	System	26 Sep 2020 20:07:48
User entered 'No (N)'	System	26 Sep 2020 20:07:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:07:30', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3b368d4f-d41f-4eb1-a62c-f879ad6b56df' User entered 'No (N)'	System	26 Sep 2020 20:07:48
	System	26 Sep 2020 20:07:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:07:40', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3b368d4f-d41f-4eb1-a62c-f879ad6b56df'	System	26 Sep 2020 20:07:48
User entered 'None (1)'	System	26 Sep 2020 20:07:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:07:44', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3b368d4f-d41f-4eb1-a62c-f879ad6b56df' User entered '26 Sep 2020 15:07'	System	26 Sep 2020 20:07:48
	System	26 Sep 2020 20:07:48

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 7'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:50:49', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3acba878-c96a-4c04-8277-8b4063595d37'	System	21 Sep 2020 17:51:29
User entered 'None (0)'	System	21 Sep 2020 17:51:29

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:50:53', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3acba878-c96a-4c04-8277-8b4063595d37'	System	21 Sep 2020 17:51:29
User entered 'None (0)'	System	21 Sep 2020 17:51:29

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:50:57', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3acba878-c96a-4c04-8277-8b4063595d37'	System	21 Sep 2020 17:51:29
User entered 'None (0)'	System	21 Sep 2020 17:51:29

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:51:02', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3acba878-c96a-4c04-8277-8b4063595d37'	System	21 Sep 2020 17:51:29
User entered 'None (0)'	System	21 Sep 2020 17:51:29

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:51:07', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3acba878-c96a-4c04-8277-8b4063595d37'	System	21 Sep 2020 17:51:29
User entered 'None (0)'	System	21 Sep 2020 17:51:29

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:51:11', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3acba878-c96a-4c04-8277-8b4063595d37'	System	21 Sep 2020 17:51:29
User entered 'None (0)'	System	21 Sep 2020 17:51:29

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:51:17', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3acba878-c96a-4c04-8277-8b4063595d37'	System	21 Sep 2020 17:51:29
User entered 'No (N)'	System	21 Sep 2020 17:51:29

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T12:51:24', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '3acba878-c96a-4c04-8277-8b4063595d37'	System	21 Sep 2020 17:51:29
User entered '21 Sep 2020 12:51'	System	21 Sep 2020 17:51:29

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Sep 2020 12:32'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Sep 2020 15:02'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:38:55', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '1c30edd1-ddc4-42be-bf54-8864c0f20cf0'	System	21 Sep 2020 21:39:40
User entered 'None (0)'	System	21 Sep 2020 21:39:40

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:39:04', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '1c30edd1-ddc4-42be-bf54-8864c0f20cf0'	System	21 Sep 2020 21:39:40
User entered 'None (0)'	System	21 Sep 2020 21:39:40

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:39:08', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '1c30edd1-ddc4-42be-bf54-8864c0f20cf0'	System	21 Sep 2020 21:39:40
User entered 'None (0)'	System	21 Sep 2020 21:39:40

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:39:14', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '1c30edd1-ddc4-42be-bf54-8864c0f20cf0'	System	21 Sep 2020 21:39:40
User entered 'None (0)'	System	21 Sep 2020 21:39:40

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:39:18', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '1c30edd1-ddc4-42be-bf54-8864c0f20cf0'	System	21 Sep 2020 21:39:40
User entered 'None (0)'	System	21 Sep 2020 21:39:40

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:39:24', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '1c30edd1-ddc4-42be-bf54-8864c0f20cf0'	System	21 Sep 2020 21:39:40
User entered 'None (0)'	System	21 Sep 2020 21:39:40

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:39:32', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '1c30edd1-ddc4-42be-bf54-8864c0f20cf0'	System	21 Sep 2020 21:39:40
User entered 'No (N)'	System	21 Sep 2020 21:39:40

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-21T16:39:37', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '1c30edd1-ddc4-42be-bf54-8864c0f20cf0' User entered '21 Sep 2020 16:39'	System	21 Sep 2020 21:39:40
	System	21 Sep 2020 21:39:40

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '21 Sep 2020 15:57'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 2'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:22:24', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5d719278-033f-4134-ad5d-4e607239572c'	System	23 Sep 2020 00:23:26
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	23 Sep 2020 00:23:26

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:22:34', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5d719278-033f-4134-ad5d-4e607239572c'	System	23 Sep 2020 00:23:26
User entered 'Some interference with activity (2)'	System	23 Sep 2020 00:23:26

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:22:44', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5d719278-033f-4134-ad5d-4e607239572c'	System	23 Sep 2020 00:23:26
User entered 'Some interference with activity (2)'	System	23 Sep 2020 00:23:26

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:22:55', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5d719278-033f-4134-ad5d-4e607239572c'	System	23 Sep 2020 00:23:26
User entered 'Some interference with activity (2)'	System	23 Sep 2020 00:23:26

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:23:01', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5d719278-033f-4134-ad5d-4e607239572c'	System	23 Sep 2020 00:23:26
User entered 'None (0)'	System	23 Sep 2020 00:23:26

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:23:10', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5d719278-033f-4134-ad5d-4e607239572c'	System	23 Sep 2020 00:23:26
User entered 'No interference with activity (1)'	System	23 Sep 2020 00:23:26

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:23:18', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5d719278-033f-4134-ad5d-4e607239572c'	System	23 Sep 2020 00:23:26
User entered 'No (N)'	System	23 Sep 2020 00:23:26

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-22T19:23:22', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5d719278-033f-4134-ad5d-4e607239572c' User entered '22 Sep 2020 19:23'	System	23 Sep 2020 00:23:26
	System	23 Sep 2020 00:23:26

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 3'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 4'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:37', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '14e45931-0e0a-43e0-9109-ef60e87e3047'	System	25 Sep 2020 01:25:11
User entered 'None (0)'	System	25 Sep 2020 01:25:11

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:40', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '14e45931-0e0a-43e0-9109-ef60e87e3047'	System	25 Sep 2020 01:25:11
User entered 'None (0)'	System	25 Sep 2020 01:25:11

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:46', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '14e45931-0e0a-43e0-9109-ef60e87e3047'	System	25 Sep 2020 01:25:11
User entered 'None (0)'	System	25 Sep 2020 01:25:11

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:50', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '14e45931-0e0a-43e0-9109-ef60e87e3047'	System	25 Sep 2020 01:25:11
User entered 'None (0)'	System	25 Sep 2020 01:25:11

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:53', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '14e45931-0e0a-43e0-9109-ef60e87e3047'	System	25 Sep 2020 01:25:11
User entered 'None (0)'	System	25 Sep 2020 01:25:11

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:24:57', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '14e45931-0e0a-43e0-9109-ef60e87e3047'	System	25 Sep 2020 01:25:11
User entered 'None (0)'	System	25 Sep 2020 01:25:11

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:25:01', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '14e45931-0e0a-43e0-9109-ef60e87e3047'	System	25 Sep 2020 01:25:11
User entered 'No (N)'	System	25 Sep 2020 01:25:11

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-24T20:25:04', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '14e45931-0e0a-43e0-9109-ef60e87e3047'	System	25 Sep 2020 01:25:11
User entered '24 Sep 2020 20:25'	System	25 Sep 2020 01:25:11

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 5'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:08:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '32a76697-9320-4b88-a2ea-118bef9c692e'	System	25 Sep 2020 19:08:41
User entered 'None (0)'	System	25 Sep 2020 19:08:41

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:08:04', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '32a76697-9320-4b88-a2ea-118bef9c692e'	System	25 Sep 2020 19:08:41
User entered 'None (0)'	System	25 Sep 2020 19:08:41

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:08:09', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '32a76697-9320-4b88-a2ea-118bef9c692e'	System	25 Sep 2020 19:08:41
User entered 'None (0)'	System	25 Sep 2020 19:08:41

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:08:17', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '32a76697-9320-4b88-a2ea-118bef9c692e'	System	25 Sep 2020 19:08:41
User entered 'None (0)'	System	25 Sep 2020 19:08:41

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:08:23', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '32a76697-9320-4b88-a2ea-118bef9c692e'	System	25 Sep 2020 19:08:41
User entered 'None (0)'	System	25 Sep 2020 19:08:41

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:08:26', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '32a76697-9320-4b88-a2ea-118bef9c692e'	System	25 Sep 2020 19:08:41
User entered 'None (0)'	System	25 Sep 2020 19:08:41

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:08:31', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '32a76697-9320-4b88-a2ea-118bef9c692e'	System	25 Sep 2020 19:08:41
User entered 'No (N)'	System	25 Sep 2020 19:08:41

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-25T14:08:36', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '32a76697-9320-4b88-a2ea-118bef9c692e'	System	25 Sep 2020 19:08:41
User entered '25 Sep 2020 14:08'	System	25 Sep 2020 19:08:41

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 6'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:07:50', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd80e4c49-5860-4bf7-9ffa-4810ad418f61'	System	26 Sep 2020 20:08:25
User entered 'None (0)'	System	26 Sep 2020 20:08:25

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:07:54', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd80e4c49-5860-4bf7-9ffa-4810ad418f61'	System	26 Sep 2020 20:08:25
User entered 'None (0)'	System	26 Sep 2020 20:08:25

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:07:59', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd80e4c49-5860-4bf7-9ffa-4810ad418f61'	System	26 Sep 2020 20:08:25
User entered 'None (0)'	System	26 Sep 2020 20:08:25

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:08:05', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd80e4c49-5860-4bf7-9ffa-4810ad418f61'	System	26 Sep 2020 20:08:25
User entered 'None (0)'	System	26 Sep 2020 20:08:25

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:08:10', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd80e4c49-5860-4bf7-9ffa-4810ad418f61'	System	26 Sep 2020 20:08:25
User entered 'None (0)'	System	26 Sep 2020 20:08:25

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:08:13', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd80e4c49-5860-4bf7-9ffa-4810ad418f61'	System	26 Sep 2020 20:08:25
User entered 'None (0)'	System	26 Sep 2020 20:08:25

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:08:16', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd80e4c49-5860-4bf7-9ffa-4810ad418f61'	System	26 Sep 2020 20:08:25
User entered 'No (N)'	System	26 Sep 2020 20:08:25

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-09-26T15:08:20', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd80e4c49-5860-4bf7-9ffa-4810ad418f61'	System	26 Sep 2020 20:08:25
User entered '26 Sep 2020 15:08'	System	26 Sep 2020 20:08:25

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	21 Sep 2020 17:15:56
User entered 'Day 7'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:15:56

US3342127

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:08:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:15:56

US3342127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:49:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 15:31:33

US3342127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:49:00
User entered '29 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 15:31:33

US3342127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:49:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 15:31:33

US3342127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:49:00
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:31:33

US3342127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:49:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 15:31:38

US3342127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '1'	System	05 Oct 2020 15:31:38

US3342127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:53:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 15:31:47

US3342127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:53:22
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 15:31:47

US3342127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:53:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 15:31:47

US3342127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:53:22
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:31:47

US3342127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:55:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:34:10

US3342127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'I'	System	12 Oct 2020 18:34:10

US3342127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:57:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:34:22

US3342127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:57:24
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:34:22

US3342127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:57:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 18:34:22

US3342127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:57:24
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:34:22

US3342127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:58:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:34:26

US3342127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'I'	System	12 Oct 2020 18:34:26

US3342127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:01:40
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:18:45

US3342127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:01:40
User entered '22 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:18:45

US3342127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:01:40
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:18:45

US3342127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'VISIT3'	System	29 Oct 2020 22:18:45

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered '22 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered '10:17'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '22 Oct 2020 10:17'	System	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered '98.2' F	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered 'Oral (Oral)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered empty.	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered '71'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'bpm'	System	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered '12'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'breaths/min'	System	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered '153'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:06
User entered '94'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'mmHg'	System	29 Oct 2020 22:19:18

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33

US3342127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33

US3342127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:20:00

US3342127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:15
User entered '22 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:20:00

US3342127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:37
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:20:19

US3342127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:37
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 22-OCT-2020. However, collection date is missing in GCL. Please confirm if 22-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:31:38
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 22-OCT-2020. However, collection date is missing in GCL. Please confirm if 22-OCT-2020 is correct date to update in GCL records.' answered with 'Visit 3 Day 57 collection date confirmed as 22-OCT-2020.' (Site from DM).	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 20:16:01
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 22-OCT-2020. However, collection date is missing in GCL. Please confirm if 22-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:18:09
User entered '22 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:20:19

US3342127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:37
User entered '10:41'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:20:19

US3342127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '22 Oct 2020 10:41'	System	29 Oct 2020 22:20:19

US3342127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:02:41
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 22:20:27

US3342127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered '1'	System	29 Oct 2020 22:20:27

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 64'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-10-23T13:24:44', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '9b0106b6-6a9f-48d3-8175-1c61fc0ae62c'	System	23 Oct 2020 18:25:10
User entered 'No (N)'	System	23 Oct 2020 18:25:10

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-10-23T13:24:50', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '9b0106b6-6a9f-48d3-8175-1c61fc0ae62c'	System	23 Oct 2020 18:25:10
User entered 'No (N)'	System	23 Oct 2020 18:25:10

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-10-23T13:25:07', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '9b0106b6-6a9f-48d3-8175-1c61fc0ae62c'	System	23 Oct 2020 18:25:10
User entered '23 Oct 2020 13:25:07'	System	23 Oct 2020 18:25:10

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 71'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-10-27T04:09:54', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '2f9015a3-fbee-48c1-91d0-5e3e3c98eb47'	System	27 Oct 2020 09:10:44
User entered 'No (N)'	System	27 Oct 2020 09:10:44

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-10-27T04:10:07', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '2f9015a3-fbee-48c1-91d0-5e3e3c98eb47'	System	27 Oct 2020 09:10:44
User entered 'No (N)'	System	27 Oct 2020 09:10:44

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-10-27T04:10:41', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '2f9015a3-fbee-48c1-91d0-5e3e3c98eb47'	System	27 Oct 2020 09:10:44
User entered '27 Oct 2020 04:10:41'	System	27 Oct 2020 09:10:44

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 78'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-11-04T16:25:24', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'e7ca4aec-aea6-4443-b54c-922d88c523df'	System	04 Nov 2020 22:25:44
User entered 'No (N)'	System	04 Nov 2020 22:25:44

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-11-04T16:25:34', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'e7ca4aec-aea6-4443-b54c-922d88c523df'	System	04 Nov 2020 22:25:44
User entered 'No (N)'	System	04 Nov 2020 22:25:44

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-11-04T16:25:39', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'e7ca4aec-aea6-4443-b54c-922d88c523df' User entered '04 Nov 2020 16:25:39'	System	04 Nov 2020 22:25:44
	System	04 Nov 2020 22:25:44

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered 'Day 92'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-11-17T00:02:42', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8f47696d-363f-4a29-a490-05709ee8e574'	System	17 Nov 2020 06:03:07
User entered 'No (N)'	System	17 Nov 2020 06:03:07

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-11-17T00:02:49', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8f47696d-363f-4a29-a490-05709ee8e574'	System	17 Nov 2020 06:03:07
User entered 'No (N)'	System	17 Nov 2020 06:03:07

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-11-17T00:03:03', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8f47696d-363f-4a29-a490-05709ee8e574'	System	17 Nov 2020 06:03:07
User entered '17 Nov 2020 00:03:03'	System	17 Nov 2020 06:03:07

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 17:37:51

US3342127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:48:14
Data entry locked.	System	20 Aug 2020 17:37:51
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 17:37:51

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2020-11-24T17:03:40', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '170e179a-4efc-4137-87e1-9c538d553178'	System	24 Nov 2020 23:03:56
User entered 'No (N)'	System	24 Nov 2020 23:03:56

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2020-11-24T17:03:46', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '170e179a-4efc-4137-87e1-9c538d553178'	System	24 Nov 2020 23:03:56
User entered 'No (N)'	System	24 Nov 2020 23:03:56

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-11-24T17:03:52', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '170e179a-4efc-4137-87e1-9c538d553178'	System	24 Nov 2020 23:03:56
User entered '24 Nov 2020 17:03:52'	System	24 Nov 2020 23:03:56

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2020-11-30T17:08:26', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'ecbdfcc6-8ee1-4253-89ed-e9a5504481a8'	System	30 Nov 2020 23:08:46
User entered 'No (N)'	System	30 Nov 2020 23:08:46

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2020-11-30T17:08:36', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'ecbdfcc6-8ee1-4253-89ed-e9a5504481a8'	System	30 Nov 2020 23:08:46
User entered 'No (N)'	System	30 Nov 2020 23:08:46

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-11-30T17:08:41', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'ecbdfcc6-8ee1-4253-89ed-e9a5504481a8'	System	30 Nov 2020 23:08:46
User entered '30 Nov 2020 17:08:41'	System	30 Nov 2020 23:08:46

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2020-12-05T00:10:52', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '31e5e1ef-e2a8-4d05-9561-be70d190056f'	System	05 Dec 2020 06:11:41
User entered 'No (N)'	System	05 Dec 2020 06:11:41

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2020-12-05T00:11:18', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '31e5e1ef-e2a8-4d05-9561-be70d190056f'	System	05 Dec 2020 06:11:41
User entered 'No (N)'	System	05 Dec 2020 06:11:41

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-12-05T00:11:36', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '31e5e1ef-e2a8-4d05-9561-be70d190056f' User entered '05 Dec 2020 00:11:36'	System	05 Dec 2020 06:11:41
	System	05 Dec 2020 06:11:41

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2020-12-12T02:02:47', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'f09e3687-84f5-4673-a6b3-996454e74875'	System	12 Dec 2020 08:03:13
User entered 'No (N)'	System	12 Dec 2020 08:03:13

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2020-12-12T02:02:54', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'f09e3687-84f5-4673-a6b3-996454e74875'	System	12 Dec 2020 08:03:13
User entered 'No (N)'	System	12 Dec 2020 08:03:13

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-12-12T02:03:10', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'f09e3687-84f5-4673-a6b3-996454e74875'	System	12 Dec 2020 08:03:13
User entered '12 Dec 2020 02:03:10'	System	12 Dec 2020 08:03:13

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2020-12-22T10:06:34', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5c32093d-18b1-49cb-9208-f8beb613923e'	System	22 Dec 2020 16:06:54
User entered 'No (N)'	System	22 Dec 2020 16:06:54

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2020-12-22T10:06:40', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5c32093d-18b1-49cb-9208-f8beb613923e'	System	22 Dec 2020 16:06:54
User entered 'No (N)'	System	22 Dec 2020 16:06:54

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-12-22T10:06:48', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5c32093d-18b1-49cb-9208-f8beb613923e'	System	22 Dec 2020 16:06:54
User entered '22 Dec 2020 10:06:48'	System	22 Dec 2020 16:06:54

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2020-12-26T20:25:41', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c0101a65-5bfe-4022-8886-e2cc90555132'	System	27 Dec 2020 02:26:13
User entered 'No (N)'	System	27 Dec 2020 02:26:13

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2020-12-26T20:25:52', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c0101a65-5bfe-4022-8886-e2cc90555132'	System	27 Dec 2020 02:26:13
User entered 'No (N)'	System	27 Dec 2020 02:26:13

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2020-12-26T20:26:08', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c0101a65-5bfe-4022-8886-e2cc90555132'	System	27 Dec 2020 02:26:13
User entered '26 Dec 2020 20:26:08'	System	27 Dec 2020 02:26:13

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-01-02T00:02:52', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered 'Yes (Y)'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-01-02T00:03:07', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered 'No (N)'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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 (03ceee92d1f1ca99)', Time: '2021-01-02T00:03:36', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered 'Yes (Y)'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '1'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '1'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '0'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '1'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '1'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '1'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '0'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '0'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '0'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '0'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '0'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '1'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '0'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '1'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '1'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '0'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '1'	System	02 Jan 2021 06:05:32

US3342127

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

Please 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 (03ceee92d1f1ca99)', Time: '2021-01-02T00:04:59', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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 (03ceee92d1f1ca99)', Time: '2021-01-02T00:05:13', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered 'No (N)'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-02T00:05:19', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8344047f-6206-4d5b-b938-62b54c17439b'	System	02 Jan 2021 06:05:32
User entered '02 Jan 2021 00:05:19'	System	02 Jan 2021 06:05:32

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-01-10T22:42:01', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'dd38a574-9a06-4d07-8974-b36ba0eccf33'	System	11 Jan 2021 04:42:16
User entered 'No (N)'	System	11 Jan 2021 04:42:16

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-01-10T22:42:08', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'dd38a574-9a06-4d07-8974-b36ba0eccf33'	System	11 Jan 2021 04:42:16
User entered 'No (N)'	System	11 Jan 2021 04:42:16

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-10T22:42:12', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'dd38a574-9a06-4d07-8974-b36ba0eccf33'	System	11 Jan 2021 04:42:16
User entered '10 Jan 2021 22:42:12'	System	11 Jan 2021 04:42:16

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-01-16T18:32:01', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c0ab0638-6945-47cd-b31b-2fe92d9fc695'	System	17 Jan 2021 00:32:22
User entered 'No (N)'	System	17 Jan 2021 00:32:22

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-01-16T18:32:13', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c0ab0638-6945-47cd-b31b-2fe92d9fc695'	System	17 Jan 2021 00:32:22
User entered 'No (N)'	System	17 Jan 2021 00:32:22

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-16T18:32:18', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'c0ab0638-6945-47cd-b31b-2fe92d9fc695'	System	17 Jan 2021 00:32:22
User entered '16 Jan 2021 18:32:18'	System	17 Jan 2021 00:32:22

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-01-23T03:58:32', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8eb90a0e-71b7-4dd7-b7db-6bbade080c68'	System	23 Jan 2021 09:59:03
User entered 'No (N)'	System	23 Jan 2021 09:59:03

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-01-23T03:58:44', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8eb90a0e-71b7-4dd7-b7db-6bbade080c68'	System	23 Jan 2021 09:59:03
User entered 'No (N)'	System	23 Jan 2021 09:59:03

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-01-23T03:59:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '8eb90a0e-71b7-4dd7-b7db-6bbade080c68'	System	23 Jan 2021 09:59:03
User entered '23 Jan 2021 03:59:00'	System	23 Jan 2021 09:59:03

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-02-01T13:38:22', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '823cdc32-260a-4907-9ae1-c009d6e961a9'	System	01 Feb 2021 19:39:09
User entered 'No (N)'	System	01 Feb 2021 19:39:09

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-02-01T13:38:30', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '823cdc32-260a-4907-9ae1-c009d6e961a9'	System	01 Feb 2021 19:39:09
User entered 'No (N)'	System	01 Feb 2021 19:39:09

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-02-01T13:38:37', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '823cdc32-260a-4907-9ae1-c009d6e961a9'	System	01 Feb 2021 19:39:09
User entered '01 Feb 2021 13:38:37'	System	01 Feb 2021 19:39:09

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-02-06T00:02:31', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fd13155f-72bb-49ab-b884-baa1d4b9bf2d'	System	06 Feb 2021 06:02:53
User entered 'No (N)'	System	06 Feb 2021 06:02:53

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-02-06T00:02:41', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fd13155f-72bb-49ab-b884-baa1d4b9bf2d'	System	06 Feb 2021 06:02:53
User entered 'No (N)'	System	06 Feb 2021 06:02:53

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-02-06T00:02:48', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fd13155f-72bb-49ab-b884-baa1d4b9bf2d'	System	06 Feb 2021 06:02:53
User entered '06 Feb 2021 00:02:48'	System	06 Feb 2021 06:02:53

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-02-17T01:13:35', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '6ed82d10-ec9b-410d-956a-5a265c7f5fe9'	System	17 Feb 2021 07:13:56
User entered 'No (N)'	System	17 Feb 2021 07:13:56

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-02-17T01:13:43', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '6ed82d10-ec9b-410d-956a-5a265c7f5fe9'	System	17 Feb 2021 07:13:56
User entered 'No (N)'	System	17 Feb 2021 07:13:56

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-02-17T01:13:51', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '6ed82d10-ec9b-410d-956a-5a265c7f5fe9'	System	17 Feb 2021 07:13:56
User entered '17 Feb 2021 01:13:51'	System	17 Feb 2021 07:13:56

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-02-20T21:28:54', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '6ceff54a-7367-4aa5-b98a-ccaed6297fc1'	System	21 Feb 2021 03:33:09
User entered 'No (N)'	System	21 Feb 2021 03:33:09

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-02-20T21:29:38', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '6ceff54a-7367-4aa5-b98a-ccaed6297fc1'	System	21 Feb 2021 03:33:09
User entered 'No (N)'	System	21 Feb 2021 03:33:09

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-02-20T21:33:05', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '6ceff54a-7367-4aa5-b98a-ccaed6297fc1' User entered '20 Feb 2021 21:33:05'	System	21 Feb 2021 03:33:09
	System	21 Feb 2021 03:33:09

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-03-06T19:48:00-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'be025e65-10df-446d-98ed-4149090a67bf'	System	07 Mar 2021 01:49:29
User entered 'Yes (Y)'	System	07 Mar 2021 01:49:29

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-03-06T19:48:16-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'be025e65-10df-446d-98ed-4149090a67bf'	System	07 Mar 2021 01:49:29
User entered 'No (N)'	System	07 Mar 2021 01:49:29

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-03-06T19:48:26-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'be025e65-10df-446d-98ed-4149090a67bf'	System	07 Mar 2021 01:49:29
User entered 'No (N)'	System	07 Mar 2021 01:49:29

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

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 (03ceee92d1f1ca99)', Time: '2021-03-06T19:48:41-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'be025e65-10df-446d-98ed-4149090a67bf'	System	07 Mar 2021 01:49:29
User entered 'Yes (Y)'	System	07 Mar 2021 01:49:29

US3342127

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:08:04**

Please 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 (03ceee92d1f1ca99)', Time: '2021-03-06T19:49:02-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'be025e65-10df-446d-98ed-4149090a67bf'	System	07 Mar 2021 01:49:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Mar 2021 01:49:29

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-03-06T19:49:18-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'be025e65-10df-446d-98ed-4149090a67bf'	System	07 Mar 2021 01:49:29
User entered '06 Mar 2021 19:49:18'	System	07 Mar 2021 01:49:29

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-03-13T00:36:26-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '25934ba0-e889-4d8d-b6da-14ba12cba79d'	System	13 Mar 2021 06:36:51
User entered 'No (N)'	System	13 Mar 2021 06:36:51

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-03-13T00:36:32-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '25934ba0-e889-4d8d-b6da-14ba12cba79d'	System	13 Mar 2021 06:36:51
User entered 'No (N)'	System	13 Mar 2021 06:36:51

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-03-13T00:36:47-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '25934ba0-e889-4d8d-b6da-14ba12cba79d' User entered '13 Mar 2021 00:36:47'	System	13 Mar 2021 06:36:51
	System	13 Mar 2021 06:36:51

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-03-20T21:24:15-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fabb0ace-6f73-45b3-afcf-06b26d835f3b'	System	21 Mar 2021 02:24:30
User entered 'No (N)'	System	21 Mar 2021 02:24:30

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-03-20T21:24:20-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fabb0ace-6f73-45b3-afcf-06b26d835f3b'	System	21 Mar 2021 02:24:30
User entered 'No (N)'	System	21 Mar 2021 02:24:30

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-03-20T21:24:26-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'fabb0ace-6f73-45b3-afcf-06b26d835f3b' User entered '20 Mar 2021 21:24:26'	System	21 Mar 2021 02:24:30

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-03-29T11:06:09-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '6c7920bf-9a88-4b0c-8893-b05ce82f9147'	System	29 Mar 2021 16:13:01
User entered 'No (N)'	System	29 Mar 2021 16:13:01

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-03-29T11:06:15-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '6c7920bf-9a88-4b0c-8893-b05ce82f9147'	System	29 Mar 2021 16:13:01
User entered 'No (N)'	System	29 Mar 2021 16:13:01

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-03-29T11:06:21-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '6c7920bf-9a88-4b0c-8893-b05ce82f9147'	System	29 Mar 2021 16:13:01
User entered '29 Mar 2021 11:06:21'	System	29 Mar 2021 16:13:01

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-04-03T15:41:44-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5c14f759-584b-4bc3-b6ae-4a4f74b133f6'	System	03 Apr 2021 20:42:03
User entered 'No (N)'	System	03 Apr 2021 20:42:03

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-04-03T15:41:52-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5c14f759-584b-4bc3-b6ae-4a4f74b133f6'	System	03 Apr 2021 20:42:03
User entered 'No (N)'	System	03 Apr 2021 20:42:03

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-04-03T15:41:58-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '5c14f759-584b-4bc3-b6ae-4a4f74b133f6'	System	03 Apr 2021 20:42:03
User entered '03 Apr 2021 15:41:58'	System	03 Apr 2021 20:42:03

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-04-13T06:50:00-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '17b68671-7b7c-41ff-b939-2e6d94aa67a2'	System	13 Apr 2021 11:50:19
User entered 'No (N)'	System	13 Apr 2021 11:50:19

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-04-13T06:50:06-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '17b68671-7b7c-41ff-b939-2e6d94aa67a2'	System	13 Apr 2021 11:50:19
User entered 'No (N)'	System	13 Apr 2021 11:50:19

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-04-13T06:50:13-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '17b68671-7b7c-41ff-b939-2e6d94aa67a2'	System	13 Apr 2021 11:50:19
User entered '13 Apr 2021 06:50:13'	System	13 Apr 2021 11:50:19

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-04-21T15:40:29-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd5173002-d40a-4c60-a021-7a0338e55bb4'	System	21 Apr 2021 20:40:48
User entered 'No (N)'	System	21 Apr 2021 20:40:48

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-04-21T15:40:34-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd5173002-d40a-4c60-a021-7a0338e55bb4'	System	21 Apr 2021 20:40:48
User entered 'No (N)'	System	21 Apr 2021 20:40:48

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-04-21T15:40:40-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'd5173002-d40a-4c60-a021-7a0338e55bb4'	System	21 Apr 2021 20:40:48
User entered '21 Apr 2021 15:40:40'	System	21 Apr 2021 20:40:48

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[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 (03ceee92d1f1ca99)', Time: '2021-04-24T20:38:05-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'b097db79-b361-4c9a-aeb7-6429c7273e8a'	System	25 Apr 2021 01:38:20
User entered 'No (N)'	System	25 Apr 2021 01:38:20

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

Have you been exposed to someone with 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 (03ceee92d1f1ca99)', Time: '2021-04-24T20:38:11-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'b097db79-b361-4c9a-aeb7-6429c7273e8a'	System	25 Apr 2021 01:38:20
User entered 'No (N)'	System	25 Apr 2021 01:38:20

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-04-24T20:38:14-05:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: 'b097db79-b361-4c9a-aeb7-6429c7273e8a'	System	25 Apr 2021 01:38:20
User entered '24 Apr 2021 20:38:14'	System	25 Apr 2021 01:38:20

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:51:36

US3342127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:51:36
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:51:36

US3342127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:08:04

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)	25 Apr 2021 02:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-03-06T19:49:35-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '89475259-8bad-4057-93e7-90426e7f1e2d'	System	07 Mar 2021 01:50:08
User entered 'No (N)'	System	07 Mar 2021 01:50:08

US3342127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:08:04

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03ceee92d1f1ca99)', Time: '2021-03-06T19:50:04-06:00', User OID: 'PatientReportedOutcome (US3342127)', ODM File OID: '89475259-8bad-4057-93e7-90426e7f1e2d' User entered '06 Mar 2021 19:50:04'	System	07 Mar 2021 01:50:08
	System	07 Mar 2021 01:50:08

US3342127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:42:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:10:05

US3342127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:42:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:10:05

US3342127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:42:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:10:05

US3342127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:42:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:10:05

US3342127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:43:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:10:11

US3342127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:27:33
User entered 'I'	System	13 Nov 2020 20:10:11

US3342127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:43:14
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:19:28

US3342127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:43:14
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:19:28

US3342127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:43:14
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:19:28

US3342127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:43:14
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:19:28

US3342127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:43:18
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:19:33

US3342127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
User entered 'I'	System	17 Dec 2020 17:19:33

US3342127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:45:26
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:17

US3342127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:45:26
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:17

US3342127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:45:26
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:17

US3342127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:45:26
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:17

US3342127

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:45:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:23

US3342127

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:59:40
User entered '1'	System	24 Feb 2021 16:52:23

US3342127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:47
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:46:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:35

US3342127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:47
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:46:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:30
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'OOW DUE TO STATE OF EMERGENCY. PLEASE REMOVE QUERY. THANK YOU' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 16:53:17
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Feb 2021 16:52:35
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 16:52:35

US3342127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:47
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:46:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:35

US3342127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:47
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:46:38
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:52:35

US3342127

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:47
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:46:47
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:55:17

US3342127

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:47
User entered '1'	System	24 Feb 2021 16:55:17

US3342127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:22:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:15:07

US3342127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:22:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '10 Mar 2021'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:15:07

US3342127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:22:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:15:07

US3342127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'VISIT4'	System	10 Mar 2021 20:15:07

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered '10 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered '09:49'	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '10 Mar 2021 09:49'	System	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered '98.0' F	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered '83'	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'bpm'	System	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered '12'	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'breaths/min'	System	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered '128'	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'mmHg'	System	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:22:37
User entered '81'	(b) (4), (b) (6)	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'mmHg'	System	31 Mar 2021 21:08:46

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07

US3342127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07

US3342127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:22:43
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:15:17

US3342127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:22:43
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '10 Mar 2021'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:15:17

US3342127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:22:49
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10-Mar-2021 is recorded under Visit 4 Day 209 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	31 Mar 2021 10:12:28
' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10-Mar-2021 is recorded under Visit 4 Day 209 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	Olivia Hapanowicz (b) (4) (b) (4)	23 Mar 2021 15:54:29
' answered with 'sample received, req number 1F605107215' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10-Mar-2021 is recorded under Visit 4 Day 209 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	23 Mar 2021 05:56:24
' (Site from DM). User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:35:58

US3342127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:22:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '10 Mar 2021'	(b) (4) Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:35:58

US3342127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:22:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '10:19'	(b) (4) Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:35:58

US3342127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered '10 Mar 2021 10:19'	System	11 Mar 2021 13:35:58

US3342127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:22:54
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	10 Mar 2021 20:15:24

US3342127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:30:07
User entered 'I'	System	10 Mar 2021 20:15:24

US3342127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	16 Apr 2021 14:17:19

US3342127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered '16 Apr 2021'	Stefanie Mott (b) (4)	16 Apr 2021 14:17:19

US3342127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Mott (b) (4)	16 Apr 2021 14:17:19

US3342127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User entered empty.	(b) (4) Stefanie Mott (b) (4)	16 Apr 2021 14:17:19

US3342127

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	16 Apr 2021 14:17:23

US3342127

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:04

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:17:23

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US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:04

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:58
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:24:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '06 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:14:35

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:04

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:58
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:24:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '08:30'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:14:35

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:04

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:58
User entered '06 Jan 2021 08:30'	System	06 Jan 2021 16:14:35

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:04

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:58
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:24:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:14:35

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:04

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:58
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:24:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:14:35

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 1 (Day 1)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '30 Dec 2020'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '101.5' F	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:22:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 2 (Day 2)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '31 Dec 2020'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:03

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 3 (Day 3)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '01 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	06 Jan 2021 16:24:36

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:42:33
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:41:26
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:41:26
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:42:51
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:24:36
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 4 (Day 4)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '02 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:25:05

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:42:24
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:41:45
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:41:45
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:44:40
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:05
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 5 (Day 5)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '03 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:42:15
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:41:57
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:41:57
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 16:43:04
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:25:30
	(b) (4)	

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 6 (Day 6)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '04 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:43:25

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	06 Jan 2021 16:43:25

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:25

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 7 (Day 7)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '05 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:43:41

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 8 (Day 8)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '06 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '99'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.3' F	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Darrell O'Brien (b) (4)	06 Jan 2021 16:44:10

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 9 (Day 9)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '7 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '100'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.8' F	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	07 Jan 2021 23:35:58

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 10 (Day 10)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '8 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '99'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.5' F	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:20:46

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 11 (Day 11)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '9 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '99'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '99.1' F	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:34:40

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 12 (Day 12)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '10 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '99'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	11 Jan 2021 14:17:21

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.1' F	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 14:17:21

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 13 (Day 13)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '11 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '97'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.3' F	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 00:10:49

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 14 (Day 14)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '12 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '100'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.6' F	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	13 Jan 2021 15:28:54

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 15 (Day 15)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '13 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '99'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.6' F	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	14 Jan 2021 15:21:56

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 16 (Day 16)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '14 Jan 2021'	Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '99'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.7' F	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 16:37:32

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 17 (Day 17)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '15 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '100'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.6' F	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	16 Jan 2021 23:38:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 18 (Day 18)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '16 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '100'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.7' F	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:03:06

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 19 (Day 19)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '17 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.5' F	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 15:20:20

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Day 20 (Day 20)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '18 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
User entered '%'	System	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.6' F	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:08:04

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Jan 2021 14:17:02

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:20
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '6 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:20
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:20
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:20
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '6 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:20
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:20
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[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)	30 Apr 2021 18:09:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:20
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:20
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:20
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:04

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:11
User entered '0'	System	26 Jan 2021 15:13:51

US3342127

Folder: Covid-19 Assessment 06 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:08:04

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:16
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:25:27
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:08:42
User entered 'No (N)'	(b) (4) Ethan Shotton (b) (4) (b) (4)	29 Mar 2021 15:02:32

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:04

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:04

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '8 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:04

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Stefanie Mott (b) (4) [REDACTED]	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:04

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '10 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:04

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:04

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '12 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:04

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Stefanie Mott (b) (4) [REDACTED]	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:04

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '14 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:04

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:04

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '19 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:04

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Stefanie Mott (b) (4) [REDACTED]	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:04

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:04

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:04

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:04

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:01:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Stefanie Mott (b) (4)	26 Jan 2021 16:07:37

US3342127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:11:53

US3342127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '06 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:11:53

US3342127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Clinic (Clinic)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:11:53

US3342127

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
User entered 'SICKD1'	System	06 Jan 2021 16:11:53

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '06 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '09:00'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
User entered '06 Jan 2021 09:00'	System	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:12:29
DataPoint set to visible.	(b) (4) System	06 Jan 2021 16:11:53

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:12:29
DataPoint set to visible.	(b) (4) System	06 Jan 2021 16:11:53

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '98.3' F	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Oral (Oral)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '83'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
User entered 'bpm'	System	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '14'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
User entered 'breaths/min'	System	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '127'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
User entered 'mmHg'	System	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:55:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '78'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
User entered 'mmHg'	System	06 Jan 2021 16:12:29

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16

US3342127

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:04

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16

US3342127

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:56:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:39

US3342127

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:56:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '06 Jan 2021'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 16:12:39

US3342127

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:08:04

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:51:51
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	12 Jan 2021 22:35:27

US3342127

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:08:04

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:51:51
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 06 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 10:33:56
Query 'Per Lab Recon: SARS-COV2: Sample dated 06 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'sample 1F634205782 accessioned as draw date 08jan2021 in error req ID 1F655009304' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	05 Feb 2021 16:50:51
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 06 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 12:22:20

US3342127

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:08:04

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '06 Jan 2021'	Eileen Euperio (b) (4) (b) (4)	12 Jan 2021 22:35:27

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:43
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:53:44

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:43
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '29 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:53:44

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:43
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Clinic (Clinic)'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:53:44

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 15:53:44

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '29 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:54:01

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Ethan Shotton (b) (4)	08 Mar 2021 14:07:55
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 17:10:14

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:54:01

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Amendment 6 or later (Amendment 6 or later)'	Ethan Shotton (b) (4)	08 Mar 2021 14:07:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:10:14

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '29 Jan 2021'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:54:01

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:54:01

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:54:01

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:54:01

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:49
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	29 Jan 2021 15:54:01

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
User entered empty.	System	29 Jan 2021 15:54:01

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:08:04

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
User entered empty.	System	29 Jan 2021 15:54:01

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 29JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 11:07:04
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 29JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' answered with 'sample was received, req number 1F621693659' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	12 Feb 2021 17:51:25
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 29JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 16:21:56
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	02 Feb 2021 16:43:08

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '29 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	02 Feb 2021 16:43:08

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:50:55
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '09:50'	(b) (4) Eileen Euperio (b) (4)	02 Feb 2021 16:43:08

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
User entered '29 Jan 2021 09:50'	System	02 Feb 2021 16:43:08

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:51:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	02 Feb 2021 16:43:17

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:51:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '29 Jan 2021'	(b) (4) Eileen Euperio (b) (4)	02 Feb 2021 16:43:17

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:51:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '09:51'	(b) (4) Eileen Euperio (b) (4) (b) (4)	02 Feb 2021 16:43:17

US3342127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:04

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:16
User entered '29 Jan 2021 09:51'	System	02 Feb 2021 16:43:17

US3342127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:08:04

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:27
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:25
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:34:52
User entered 'Yes (Y)'	(b) (4) Olivia Hapanowicz (b) (4)	11 Nov 2020 20:33:05

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:53:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:53:37
Data point term sent to Coder	System	11 Nov 2020 20:52:54
User entered 'Syncope'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '08 Oct 2020'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:52:21

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US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User closed query 'Per DM CLR: Please review the duration of this AE, it is unusual for SYNCOPE to have a duration of more than a day. Effects may continue on but not the event itself. Record any effects if present and update the date as appropriate. Otherwise, clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 05:44:04
Query 'Per DM CLR: Please review the duration of this AE, it is unusual for SYNCOPE to have a duration of more than a day. Effects may continue on but not the event itself. Record any effects if present and update the date as appropriate. Otherwise, clarify in query response. ' answered with 'End date has been corrected, EDC updated.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	25 Nov 2020 18:17:00
User entered '08 Oct 2020' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	25 Nov 2020 18:16:34
User opened query 'Per DM CLR: Please review the duration of this AE, it is unusual for SYNCOPE to have a duration of more than a day. Effects may continue on but not the event itself. Record any effects if present and update the date as appropriate. Otherwise, clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:01:43
Query 'US3342127 ' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:01:37
User opened query 'US3342127 ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:58:11
User entered '09 Oct 2020'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 20:52:21

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US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'Grade 1/Mild (Grade 1/Mild)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'Not Applicable (NOT APPLICABLE)'	Olivia Hapanowicz (b) (4)	11 Nov 2020 20:52:21
	(b) (4)	

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '1'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:52:21

US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 20:52:21

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US3342127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:04

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 20:52:21

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US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:23:15
DataPoint Un-verified.	(b) (4), (b) (6)	07 Dec 2020 20:22:32
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:22:30
DataPoint Un-verified.	(b) (4), (b) (6)	07 Dec 2020 20:22:28
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:18:37
User coded data point as SOC: Vascular disorders, HLG: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Orthostatic hypotension, LLT: Orthostatic hypotension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:54:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:54:36
Data point term sent to Coder	System	11 Nov 2020 20:53:56
User entered 'Orthostatic hypotension'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:18:41
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:19:16
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:19:42
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:19:48
User entered '08 Oct 2020'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:19:49
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
User entered empty.	System	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:20:26
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
Query 'Source states 08OCT2020. Please review and reconcile' canceled (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 20:23:17
User opened query 'Source states 08OCT2020. Please review and reconcile' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 20:20:46
User entered '09 Oct 2020'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:01
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
User entered empty.	System	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:10
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:13
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:15
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:16
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:18
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:21
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:22
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:25
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:27
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:28
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:49
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:21:57
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:22:02
User entered 'Not Applicable (NOT APPLICABLE)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:22:03
User entered '1'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:22:09
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:22:12
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:27:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:24:20
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:24:23
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
User entered '0'	System	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22
User entered '0'	System	11 Nov 2020 20:53:34

US3342127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:04

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:37:22

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:01:11
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'can confirm NOT COVID-19, causative organism UNKNOWN' (Site from DM).	Olivia Hapanowicz (b) (4)	04 Feb 2021 22:22:08
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 11:28:30
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral upper respiratory tract infection, LLT: Viral upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4)	06 Jan 2021 01:44:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Jan 2021 01:44:34
Data point term sent to Coder	System	06 Jan 2021 01:43:19
User entered 'Viral URI'	Darrell O'Brien (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '30 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 01:42:53

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US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'No (N)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	26 Jan 2021 15:19:04
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '07 Jan 2021' reason for change: Data Entry Error	Stefanie Mott (b) (4)	26 Jan 2021 15:19:04
User entered empty.	Darrell O'Brien (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 01:42:53

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US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Not Related (NOT RELATED)'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Not Related (NOT RELATED)'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Not Applicable (NOT APPLICABLE)'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 13:23:26
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'aspirin taken for viral uri ae. updated in con med list ' (Site from DM).	Stefanie Mott (b) (4)	26 Jan 2021 15:19:58
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 06:41:34
User entered '1'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	26 Jan 2021 15:19:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Darrell O'Brien (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 01:42:53

US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	06 Jan 2021 01:42:53

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US3342127

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:08:04

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 01:42:53

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US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:25:49
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'USA-US203-2021-mRNA-1273-P301000012'	System	11 Mar 2021 16:55:04
User entered 'New'	(b) (4), (b) (6)	11 Mar 2021 16:55:04

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:34:18
User closed query 'Per MM, please update the AE term to specify cause or medical diagnosis' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 13:12:18
User coded data point as SOC: Cardiac disorders, HLT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive cardiac failure aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 17:16:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 17:16:37
Query 'Per MM, please update the AE term to specify cause or medical diagnosis' answered with 'AE term updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 17:15:51
Data point term sent to Coder	System	01 Apr 2021 17:15:36
DataPoint Un-verified.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 17:15:00
Coding entries removed.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 17:15:00
User entered 'Worsening of congestive heart failure' reason for change: New Information	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 17:15:00
User opened query 'Per MM, please update the AE term to specify cause or medical diagnosis' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:28:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 20:19:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 20:19:55
Data point term sent to Coder	System	10 Mar 2021 20:19:25
User entered 'pleural effusion'	Tiffany Lemuz (b) (4) (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'No (N)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'No (N)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '1 Mar 2021'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 20:19:17

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US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:28:35
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:28:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:34:18
DataPoint Un-verified.	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:24:39
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:24:39
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'No (N)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:34:18
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	01 Apr 2021 17:25:18
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	01 Apr 2021 17:25:18
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	01 Apr 2021 17:24:39
DataPoint Un-verified.	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:24:39
User entered empty; reason for change New Information	(b) (4)	
	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:24:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '6 Mar 2021'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 20:19:17

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US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Grade 4 (Grade 4)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '1'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:33:33
DataPoint Un-verified.	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:24:39
User entered '06 Mar 2021' reason for change: New Information	(b) (4)	01 Apr 2021 17:24:39
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '1 Mar 2021'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:33:32
DataPoint Un-verified.	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:24:39
User entered '22 Mar 2021' reason for change: New Information	(b) (4)	01 Apr 2021 17:24:39
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '6 Mar 2021'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:33:28
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	01 Apr 2021 17:24:39
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	01 Apr 2021 17:24:39
DataPoint Un-verified.	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:24:39
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:24:39
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	10 Mar 2021 20:19:17
User entered 'Unknown (UNK)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Not Related (NOT RELATED)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Not Related (NOT RELATED)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Not Applicable (NOT APPLICABLE)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '0'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 13:13:00
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'corresponding con meds have been added to log' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:30:41
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:18:08
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'I'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 13:13:03
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'thoracentesis added to con procedures' (Site from DM).	Olivia Hapanowicz (b) (4)	01 Apr 2021 19:08:03
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:18:13
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered '1'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:34:04
DataPoint Un-verified.	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:25:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	(b) (4)	
Data Entry Error	Olivia Hapanowicz (b) (4)	01 Apr 2021 17:25:18
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered empty.	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:33:48
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:26:02
User entered 'PENDING MEDICAL RECORDS, PATIENT REPORTS NONCOMPLIANCE WITH CONGESTIVE HEART FAILURE MEDICATION REGIMEN LED TO PLEURAL EFFUSION. HOSPITALIZED. TESTED FOR SARS-COV-2: NEGATIVE. WILL PROVIDE FURTHER DETAILS ONCE MEDICAL RECORDS RECEIVED.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 19:08:26
CALLED PATIENT 01APRIL2021 TO GET MORE INFORMATION ABOUT SAE. PATIENT REPORTS THAT HE WAS ADMITTED TO HOSPITAL 06MAR2021 DUE TO SHORTNESS OF BREATH/DYSPNEA ON EXERTION AND DISCOVERED TO HAVE A LARGE PLEURAL EFFUSION. THORACENTESIS PERFORMED 06Mar2021 AND CYTOLOGY NEGATIVE AND WITH FURTHER STUDIES, SUPPORTING A DIAGNOSIS OF CHF AND STARTED LIPITOR (80 MG QD) AND CARVEDILOL (6.25 MG BID). STILL AWAITING MEDICAL RECORDS, WILL UPDATE ONCE RECEIVED.' reason for change: Data Entry Error		
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'thoracentesis added to con procedures' (Site from Safety).	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 19:07:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PENDING MEDICAL RECORDS, PATIENT REPORTS NONCOMPLIANCE WITH CONGESTIVE HEART FAILURE MEDICATION REGIMEN LED TO PLEURAL EFFUSION. HOSPITALIZED. TESTED FOR SARS-COV-2: NEGATIVE. WILL PROVIDE FURTHER DETAILS ONCE MEDICAL RECORDS RECEIVED.   CALLED PATIENT 01APRIL2021 TO GET MORE INFORMATION ABOUT SAE. PATIENT REPORTS THAT HE WAS ADMITTED TO HOSPITAL 06MAR2021 DUE TO SHORTNESS OF BREATH/DYSPNEA ON EXERTION AND DISCOVERED TO HAVE A LARGE PLEURAL EFFUSION. THORACENTESIS PERFORMED AND CYTOLOGY NEGATIVE AND WITH FURTHER STUDIES, SUPPORTING A DIAGNOSIS OF CHF AND STARTED LIPITOR (80 mg QD) AND CARVEDILOL (6.25 mg BID). STILL AWAITING MEDICAL RECORDS, WILL UPDATE ONCE RECEIVED.' reason for change: Data Entry Error DataPoint Un-verified.	Olivia Hapanowicz (b) (4) (b) (4)	(b) (4) 01 Apr 2021 19:04:28
	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 17:21:24
User entered 'PENDING MEDICAL RECORDS, PATIENT REPORTS NONCOMPLIANCE WITH CONGESTIVE HEART FAILURE MEDICATION REGIMEN LED TO PLEURAL EFFUSION. HOSPITALIZED. TESTED FOR SARS-COV-2: NEGATIVE. WILL PROVIDE FURTHER DETAILS ONCE MEDICAL RECORDS RECEIVED.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 17:21:24
Called patient 01April2021 to get more information about SAE. Patient reports that he was admitted to hospital 06Mar2021 due to shortness of breath/dyspnea on exertion and discovered to have a large pleural effusion. Thoracentesis performed and cytology negative and with further studies, supporting a diagnosis of CHF and started lipitor and carvedilol. Still awaiting medical records, will update once received.' reason for change: Data Entry Error		

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary including diagnostics (eg. chest X-ray/ chest CT etc) and laboratory tests with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 23:21:21
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 23:21:03
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:07
User entered 'Pending medical records, patient reports noncompliance with congestive heart failure medication regimen led to pleural effusion. Hospitalized. Tested for SARS-CoV-2: negative. Will provide further details once medical records received.'	Tiffany Lemuz (b) (4)	10 Mar 2021 20:19:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 20:19:17

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US3342127

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:08:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 20:19:17

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US3342127

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:08:04**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 20:19:17

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US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 15:31:23
User entered 'USA-US203-2021-mRNA-1273-P301000015'	System	19 Apr 2021 16:00:45
User entered 'New'	(b) (4), (b) (6)	19 Apr 2021 16:00:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:58:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:58:37
Data point term sent to Coder	System	16 Apr 2021 20:19:56
User entered 'pulmonary embolism right lung'	Stefanie Mott (b) (4) (b) (4) (b) (4)	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4) [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Apr 2021'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 20:19:07
	[REDACTED]	
	[REDACTED]	

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:19:07

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US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:25:28
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:25:09
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 20:19:07
	[REDACTED]	
	[REDACTED]	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:19:07

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US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Stefanie Mott (b) (4) [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4) [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

Death

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	16 Apr 2021 20:19:07
	[REDACTED]	
	[REDACTED]	

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User entered '1'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:24:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results including those for the chest x-ray, CT scan, ultrasound of heart and lab work done in hospital. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:24:29
User opened query 'PV Query: Please provide the date that the chest x-ray, CT scan, ultrasound of heart were performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:24:08
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 12:56:26
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospital admission date and admitted to icu entered. discharge date is left blank since pt is not discharged yet' (Site from System).	Stefanie Mott (b) (4)	16 Apr 2021 20:23:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Apr 2021 20:19:07
User entered '1'	Stefanie Mott (b) (4)	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Apr 2021'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Apr 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4)	19 Apr 2021 15:00:34
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Stefanie Mott (b) (4)	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

None

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Stefanie Mott (b) (4) [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'IQVIA Medical query: Please confirm whether subject has risk factors for the event other than prior history of deep vein thrombosis (i.e. smoker, sedentary lifestyle, trauma, immobilization, bedrest, recent surgery).' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:23:45
User entered 'SOB ONSET 11APR2021 WORSENING OVER TIME. PT REPORTS GOING TO THE HOSPITAL AT 0630 ON 16APR2021. PT STATES HE HAD CHEST XRAY, CT SCAN, U/S OF HEART, LAB WORK AND COVID TEST (PENDING RESULTS). PT WAS ADMITTED TO THE HOSPITAL DUE TO PULMONARY EMBOLISM IN RIGHT LUNG. PT WAS STARTED ON 2 NEW MEDICATIONS-SPIRONOLACTONE (UNKNOWN DOSAGE) AND LOVENOX (UNKNOWN DOSAGE). RELEASE OF MEDICAL RECORDS SENT. PENDING RECORDS.' reason for change: Data Entry Error	Stefanie Mott (b) (4)	16 Apr 2021 20:44:08
User entered 'SOB onset 11Apr2021 worsening over time. Pt reports going to the hospital at 0630 on 16Apr2021. Pt states he had chest xray, lab work and covid test (pending results). pt was admitted to the hospital due to pulmonary embolism in right lung. release of medical records sent. pending records.'	Stefanie Mott (b) (4)	16 Apr 2021 20:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 20:19:07

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US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 20:19:07

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US3342127

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:08:04

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 20:19:07

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:08:04

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User closed query 'Please add Orthostatic Hypotension to the AE page in EDC per source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 03:04:01
Query 'Please add Orthostatic Hypotension to the AE page in EDC per source.' answered with 'Orthostatic hypotension has been added to the AE page in EDC.' (Site from CRA).	Olivia Hapanowicz (b) (4) (b) (4)	12 Nov 2020 21:23:35
User opened query 'Please add Orthostatic Hypotension to the AE page in EDC per source.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 15:17:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:15:53
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	20 Aug 2020 17:38:54

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:49:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:49:30
Data point term sent to Coder User entered 'Aspirin'	System John Luna (b) (4)	20 Aug 2020 17:47:51 20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 15:16:53
User closed query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prophylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:53:51
Query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prophylaxis. Please review, reconcile, and update accordingly.' answered with 'Changed "no" to "yes" per source documentation stating the medication was being taken as a prophylaxis.' (Site from DM).	Darrell O'Brien (b) (4)	10 Sep 2020 22:49:32
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	10 Sep 2020 22:47:59
	(b) (4)	
User opened query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prophylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 11:04:32
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Cardiac Prophylaxis'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Apr 2021 15:31:17
Signature has been broken.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 19:05:26
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '81'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'mg (mg)'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:08:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'once daily (QD)'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Oral (ORAL)'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:08:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:54:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:47:11
User entered 'un UNK 2015'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '0'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Yes (Y)'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:08:04**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:08:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 17:47:11

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:47:11

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:47:11

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:47:11

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 04:26:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:32
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	29 Oct 2020 15:16:55 29 Oct 2020 15:16:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:49:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 17:49:33
Data point term sent to Coder User entered 'Buspirone Hydrochloride'	System John Luna (b) (4)	20 Aug 2020 17:48:53 20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Anxiety'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '20'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'mg (mg)'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'once daily (QD)'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Oral (ORAL)'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:54:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:48:21
User entered 'un UNK 2010'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '0'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Yes (Y)'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 17:48:21

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:48:21

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:48:21

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:48:21

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 04:26:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:26
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	29 Oct 2020 15:16:53 29 Oct 2020 15:16:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 17:51:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 17:51:25
Data point term sent to Coder User entered 'Loratidine'	System John Luna (b) (4)	20 Aug 2020 17:49:54 20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Seasonal Allergies'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '10'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'mg (mg)'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:08:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'as needed (PRN)'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Oral (ORAL)'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:54:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:49:05
User entered 'un UNK 2015'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:08:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '0'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Yes (Y)'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:08:04**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 17:49:05

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:49:05

---

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:49:05

---

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:49:05

---

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 04:26:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:33
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	29 Oct 2020 15:16:55 29 Oct 2020 15:16:53
User closed query 'Per MM, please confirm the route of administration' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:33:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 15:11:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 15:11:35
Data point term sent to Coder Query 'Per MM, please confirm the route of administration' answered with 'Medication confirmed as nasal spray. Route of administration updated.' (Site from DM).	System Andrew Bell (b) (4)	07 Oct 2020 13:40:03 07 Oct 2020 13:40:01
Coding entries removed.	Andrew Bell (b) (4)	07 Oct 2020 13:39:32
User opened query 'Per MM, please confirm the route of administration' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:14:09

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 18:03:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 18:03:19
Data point term sent to Coder	System	20 Aug 2020 18:02:29
User entered 'Fluticasone'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Seasonal Allergies'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '50'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Other (OTHER)'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'mcg'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'as needed (PRN)'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Andrew Bell (b) (4) (b) (4)	07 Oct 2020 13:39:32
User entered 'Oral (ORAL)'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:08:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:54:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:02:01
User entered 'un Jan 2020'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '0'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Yes (Y)'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:08:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 18:02:01

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:02:01

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:02:01

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:02:01

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 04:26:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:32
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	29 Oct 2020 15:16:55 29 Oct 2020 15:16:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 18:04:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 18:04:18
Data point term sent to Coder User entered 'Escitalopram'	System John Luna (b) (4)	20 Aug 2020 18:03:33 20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Depression'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '5'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'mg (mg)'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'once daily (QD)'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Oral (ORAL)'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:54:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:03:07
User entered 'un UNK 2015'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '0'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Yes (Y)'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	John Luna (b) (4)	20 Aug 2020 18:03:07

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:03:07

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:03:07

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:03:07

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 04:26:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:32
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	29 Oct 2020 15:16:56 29 Oct 2020 15:16:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 17:06:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 17:06:44
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	21 Sep 2020 17:05:33 21 Sep 2020 17:05:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 17:04:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 17:04:40

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	21 Sep 2020 17:03:25
User entered 'Aspirin'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:56:53
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'Injection site pain was an expected AR for injection #1 and did not meet AE reporting criteria.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	03 Dec 2020 18:37:34

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 16:48:23
	(b) (4), (b) (6)	29 Oct 2020 15:16:53
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:05:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 17:05:02
User entered 'Injection Site Pain' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:05:02
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 17:02:37
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '650'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '23 Aug 2020'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:02:37

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:02:37

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:02:37

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:02:37

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 04:26:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:25
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	29 Oct 2020 15:16:56 29 Oct 2020 15:16:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 22:51:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 22:51:44
Data point term sent to Coder User entered 'ASPIRIN'	System Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:45 29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'HEADACHE'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '650'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'once (ONCE)'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered empty.	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '22 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '0'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered '22 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:16:53
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	29 Sep 2020 22:50:17

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 22:50:17

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 22:50:17

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 22:50:17

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 15:20:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 15:20:14
Data point term sent to Coder Coding entries removed.	System Stefanie Mott (b) (4)	26 Jan 2021 15:19:54 26 Jan 2021 15:19:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Jan 2021 15:59:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Jan 2021 15:59:43
Data point term sent to Coder User entered 'Aspirin'	System Darrell O'Brien (b) (4)	06 Jan 2021 15:59:22 06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'No (N)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
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 if appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 09:35:41
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 if appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:34:58
User entered 'viral URI AE' reason for change: Data Entry Error	Stefanie Mott (b) (4)	26 Jan 2021 15:19:22
User entered 'Fever'	Darrell O'Brien (b) (4) (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '325'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'mg (mg)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'as needed (PRN)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'Oral (ORAL)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '30 Dec 2020'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '0'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'No (N)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '31 Dec 2020'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:49:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'No (N)'	(b) (4) Darrell O'Brien (b) (4)	06 Jan 2021 15:59:07

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 15:59:07

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 15:59:07

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 15:59:07

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:42:54
Data point term sent to Coder	System	01 Apr 2021 18:28:38
User entered 'lipitor'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'worsening of congestive heart failure SAE'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered '80'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'mg (mg)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'once daily (QD)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'Oral (ORAL)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered '22 Mar 2021'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:27:51

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:27:51

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:27:51

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 18:27:51

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:22:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:22:06
Data point term sent to Coder	System	01 Apr 2021 18:29:39
User entered 'carvedilol'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'worsening of congestive heart failure SAE'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered '6.25'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'mg (mg)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'twice daily (BID)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'Oral (ORAL)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered '22 Mar 2021'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:14
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 18:29:18

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '2'	System	01 Apr 2021 18:29:18

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:29:18

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 18:29:18

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX 23 - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	16 Apr 2021 15:32:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:32:55
Data point term sent to Coder	System	16 Apr 2021 15:32:14
User entered 'pneumovax 23'	Stefanie Mott (b) (4) (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User entered 'pneumonia prophylaxis'	(b) (4) Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered '0.5'	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'mL (mL)'	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered '12 Apr 2021'	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered '12 Apr 2021'	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	16 Apr 2021 15:31:23

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:31:23

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:31:23

---

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:31:23

---

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Apr 2021 08:11:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:11:23
Data point term sent to Coder	System	16 Apr 2021 21:51:41
User entered 'spironolactone'	Stefanie Mott (b) (4) (b) (4) (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User entered 'pulmonary embolism right lung SAE'	(b) (4) Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'UNK'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'unknown (UNKNOWN)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23
	[REDACTED]	
	[REDACTED]	

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered '16 Apr 2021'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:23

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:51:23

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:51:23

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:51:23

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US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Apr 2021 14:52:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:52:42
Data point term sent to Coder	System	16 Apr 2021 21:52:41
User entered 'lovenox'	Stefanie Mott (b) (4) (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User entered 'pulmonary embolism right lung SAE'	(b) (4) Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'unk'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'unknown (UNKNOWN)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered '16 Apr 2021'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:08:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	16 Apr 2021 21:51:58

US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:08:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:51:58

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:51:58

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US3342127

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:08:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 21:51:58

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US3342127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:08:04

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:21
Signature has been broken.	Olivia Hapanowicz (b) (4)	01 Apr 2021 18:29:46
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Olivia Hapanowicz (b) (4)	01 Apr 2021 18:29:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'No (N)'	(b) (4) Ethan Shotton (b) (4)	04 Mar 2021 17:30:53

US3342127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:04

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:28
User entered '06 Mar 2021'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 19:05:11

US3342127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:28
User entered 'thoracentesis'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 19:05:11

US3342127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:28
User entered 'Adverse Event (AE)'	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 19:05:11

US3342127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:04

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:27:28
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	01 Apr 2021 19:05:11

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'USA-US203-2021-MRNA-1273-P301000012'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Yes (Y)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Yes (Y)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Paul'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Pickrell'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:26:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'US'	(b) (4) System	11 Mar 2021 16:55:49

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 16:26:36
User entered '1'	System	11 Mar 2021 16:55:49

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US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'USA-US203-2021-MRNA-1273-P301000012'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Yes (Y)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Yes (Y)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Paul'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Pickrell'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:26:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'US'	(b) (4) System	11 Mar 2021 16:55:49

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 16:26:36
User entered '1'	System	11 Mar 2021 16:55:49

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:04

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '11/Mar/2021 11:55'	(b) (4) System	11 Mar 2021 16:55:49

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:04

**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)
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:26:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:49

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'USA-US203-2021-MRNA-1273-P301000012'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Yes (Y)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Yes (Y)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'No (N)'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Paul'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:55:33
User entered 'Pickrell'	System	11 Mar 2021 16:55:04

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 16:26:24
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:37:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:14:14
User entered 'US'	(b) (4) System	11 Mar 2021 16:55:49

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 16:26:36
User entered '1'	System	11 Mar 2021 16:55:49

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US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:08:04

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:26:59
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
User entered '02/Apr/2021 12:26'	(b) (4) System	02 Apr 2021 16:26:36

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:08:04

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 02:26:59
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:31:17
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 16:26:36

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'USA-US203-2021-MRNA-1273-P301000015'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Yes (Y)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Yes (Y)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Yes (Y)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Paul'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Pickrell'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'US'	System	19 Apr 2021 16:04:12

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 15:28:59
User entered '2'	System	20 Apr 2021 15:02:22
User entered '1'	System	19 Apr 2021 16:04:12

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'USA-US203-2021-MRNA-1273-P301000015'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Yes (Y)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Yes (Y)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Yes (Y)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Paul'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Pickrell'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'US'	System	19 Apr 2021 16:04:12

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 15:28:59
User entered '2'	System	20 Apr 2021 15:02:22
User entered '1'	System	19 Apr 2021 16:04:12

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:04

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User entered '19/Apr/2021 12:04'	(b) (4) System	19 Apr 2021 16:04:12

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:04

**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.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 16:04:12

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'USA-US203-2021-MRNA-1273-P301000015'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Yes (Y)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Yes (Y)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Yes (Y)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'No (N)'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Paul'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'Pickrell'	System	19 Apr 2021 16:00:45

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:04:14
User entered 'US'	System	19 Apr 2021 16:04:12

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 15:28:59
User entered '2'	System	20 Apr 2021 15:02:22
User entered '1'	System	19 Apr 2021 16:04:12

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:08:04

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
User entered '20/Apr/2021 15:02'	(b) (4) System	20 Apr 2021 15:02:22

US3342127

Folder: SAE USA-US203-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:08:04

**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.	Paul Pickrell (b) (4)	28 Apr 2021 16:34:58
Un-reviewed for Safety.	(b) (4)	20 Apr 2021 15:35:32
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:35:32
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 15:28:50
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 15:28:32
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:28:32
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 15:03:42
User entered '1'	(b) (4), (b) (6)	20 Apr 2021 15:02:22