

US3112121 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:11:31

All time stamps listed in this document are displayed in GMT

US3112121

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

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Participant ID

US3112121

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

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US3112121

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:46:06

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 16:46:06

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1976
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 1976
Start Year (derived)	1976
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

Condition	MELANOMA (ABD)
Start date (dd MMM yyyy)	UN DEC 2010
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 DEC 2010
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2010
Start Year (derived)	2010
Stop Month and Year (derived)	DEC 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

Condition	MELANOMA (LEFT BICEP)
Start date (dd MMM yyyy)	20 NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	20 NOV 2019
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	NOV 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	05 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:47 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 15:47
Height ( <i>xxx.x</i> )	68 in
Weight ( <i>xxx.x</i> )	167 lb
BMI ( <i>xxx.x</i> )	25.44536 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) 19 Feb 2021 16:46:06

Generated On: 09 Jun 2021 15:11:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:46:06

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:46:06

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	True
<b>Specify</b>	4-5 MEMBER FAMILY



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 101433

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 AUG 2020
Time of assessment (00:00-23:59)	15:47 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 15:47
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 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 20:49:55

Generated On: 09 Jun 2021 15:11:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 AUG 2020
Time of assessment (00:00-23:59)	17:27 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 17:27
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

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) 5 AUG 2020

What was the treatment time? (00:00-23:59) 16:50 (24 HR)

Treatment Date and Time (derived) 5 AUG 2020 16:50

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 AUG 2020
Collection time (00:00-23:59)	16:06 (24 HR)
Collection date and time (derived)	05 AUG 2020 16:06



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Collection date (dd MMM yyyy)			05 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:01	05 AUG 2020 16:01
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**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

97.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp

05 AUG 2020 17:32

PC Open Date & Time

05 AUG 2020 17:10

PC Close Date & Time

05 AUG 2020 19:40

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**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 97.9 °F

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

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

PC Time Stamp	05 AUG 2020 23:11
PC Open Date & Time	05 AUG 2020 20:35
PC Close Date & Time	06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 18:18

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:01

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**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

08 AUG 2020 15:37

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

10 AUG 2020 00:02

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59



US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 09:41

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 10:24

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 17:33

PC Open Date & Time

05 AUG 2020 17:10

PC Close Date & Time

05 AUG 2020 19:40

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**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

05 AUG 2020 23:12

PC Open Date & Time

05 AUG 2020 20:35

PC Close Date & Time

06 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 18:19

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 12:01

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 15:38

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 00:03

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59



US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 09:41

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 10:25

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**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 ☐

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 17:33
PC Open Date & Time	05 AUG 2020 17:10
PC Close Date & Time	05 AUG 2020 19:40

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**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 ☐

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 23:12
PC Open Date & Time	05 AUG 2020 20:35
PC Close Date & Time	06 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**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 ☒

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 18:19
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59



US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

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 ☒

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 12:02
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

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 ☒

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 15:38
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

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 ☒

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 00:03
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 09:41
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59



US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2068

EAB) (1725)

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 10:26
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3112121

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:53

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:53

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:53

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:53

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:53

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:53

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112121

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 14:35
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	088 mmHg
Diastolic Blood Pressure units	MMHG

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 16:00
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	072 mmHg
Diastolic Blood Pressure units	MMHG

US3112121

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 SEP 2020

What was the treatment time? (00:00-23:59) 15:27 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 15:27

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

US3112121

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	14:45 (24 HR)
Collection date and time (derived)	2 SEP 2020 14:45

US3112121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:39	2 SEP 2020 14:39
Nasopharyngeal Swab 2	No		

US3112121

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**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

98.6 °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 02 SEP 2020 16:01

PC Open Date & Time 02 SEP 2020 15:47

PC Close Date & Time 02 SEP 2020 18:17

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	02 SEP 2020 19:26
PC Open Date & Time	02 SEP 2020 19:12
PC Close Date & Time	03 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

03 SEP 2020 23:14

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**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

05 SEP 2020 16:39

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**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

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 16:54

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 15:37

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 16:03

PC Open Date & Time

02 SEP 2020 15:47

PC Close Date & Time

02 SEP 2020 18:17

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 19:27

PC Open Date & Time

02 SEP 2020 19:12

PC Close Date & Time

03 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 23:15

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 16:40

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 16:54

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 15:37

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**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 ☐

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 16:03
---------------	-------------------

PC Open Date & Time	02 SEP 2020 15:47
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PC Close Date & Time	02 SEP 2020 18:17
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US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**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 ☐

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 19:27
PC Open Date & Time	02 SEP 2020 19:12
PC Close Date & Time	03 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 23:15
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

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 ☒

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59



US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 16:41
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

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 ☒

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 16:54
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**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 ☒

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 15:38
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59



US3112121

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:53

Generated On: 09 Jun 2021 15:11:31

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

US3112121

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:53

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:55

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:49:56

Generated On: 09 Jun 2021 15:11:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:49:56

Generated On: 09 Jun 2021 15:11:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	13:42 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 13:42
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3112121

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:49:56

Generated On: 09 Jun 2021 15:11:31

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.*

US3112121

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:49:56

Generated On: 09 Jun 2021 15:11:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	14:05 (24 HR)
Collection date and time (derived)	01 OCT 2020 14:05

US3112121

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:49:56

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 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"/>
Have 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)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this 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 type="radio"/> Yes <input checked="" type="radio"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

07 OCT 2020 15:33:34

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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

14 OCT 2020 12:19:29

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 15:12:51

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 NOV 2020 07:27:18
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59



US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 12:08:47
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 00:16:23

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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

24 NOV 2020 16:29:53

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 12:00:22

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 17:59:28

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 12:00:26

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 12:26:22

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 00:01:21

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59



US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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

04 JAN 2021 18:00:57

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 00:02:17

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 10:33:37

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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	05 FEB 2021 07:28:14
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59



US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 09:08:11
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 20:40:04

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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

02 MAR 2021 10:24:02

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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	05 MAR 2021 08:19:02
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 12:31:53

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 12:00:20

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

<b>TIMEPOINT</b>	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	26 MAR 2021 15:41:47
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 243

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

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

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

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

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

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



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 18:06:45

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 08:35:55

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 08:05:58

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

Date and time of submission

02 MAY 2021 12:00:23

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUN 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUN 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUL 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 SEP 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JAN 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 MAR 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 APR 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 APR 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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12 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 AUG 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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

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 ☐



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**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 ☐

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3112121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112121**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2022 23:59

US3112121

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:11:31

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 10:24:26

US3112121

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:45:12

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:45:12

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112121

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

Visit date (dd MMM yyyy)	3 MAR 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 MAR 2021
Time of assessment (00:00-23:59)	16:25 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 16:25
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112121

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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.*

US3112121

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 3 MAR 2021

Collection time (00:00-23:59) 16:25 (24 HR)

Collection date and time (derived) 3 MAR 2021 16:25



US3112121

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112121

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3112121

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3112121**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

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*

**US3112121**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

Date of Contact	05 OCT 2020
Time of Contact	17:02
Date and Time of Contact (derived)	05 OCT 2020 17:02
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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"/>

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	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 OCT 2020
------	-------------

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

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

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 05 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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"/>

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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"/>

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 05 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	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"/>

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Symptom Day

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

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

Date	08 OCT 2020
------	-------------

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

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

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

Temperature	97.7 F
-------------	--------

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

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

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

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

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EAB) (1725)

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US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	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 05 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Symptom Day

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

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

Date	09 OCT 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	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 05 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Symptom Day

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

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	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 OCT 2020	
Assessment Not Done	True	
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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 05 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	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"/>

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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"/>

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	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 OCT 2020	
Assessment Not Done	True	
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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

	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"/>

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

Date of Visit 05 OCT 2020

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

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

Date of Test 05 OCT 2020

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

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

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

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3112121

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	07 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3112121

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

Visit date (dd MMM yyyy)	05 OCT 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 OCT 2020
Time of assessment (00:00-23:59)	17:02 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 17:02
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112121

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 OCT 2020

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

US3112121

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

05 OCT 2020



US3112121

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

Visit date (dd MMM yyyy)	21 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	UNBLND_DECIDE
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US3112121

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 22:48:48

Generated On: 09 Jun 2021 15:11:31

Date of updated informed consent (dd MMM yyyy) 21 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) 21 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 \_\_\_\_\_

US3112121

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

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

Collection date (dd MMM yyyy)	21 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:20 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	21 JAN 2021 10:20
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US3112121

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	10:14
Collection Date and Time (derived)	21 JAN 2021 10:14

US3112121

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:20:36

Generated On: 09 Jun 2021 15:11:31

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:20:36

Generated On: 09 Jun 2021 15:11:31

AEID	USA-US062-2020-MRNA-1273-P30 1000005
Adverse event	MELANOMA
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)	09 SEP 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)	21 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:20:36

Generated On: 09 Jun 2021 15:11:31

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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	

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:20:36

Generated On: 09 Jun 2021 15:11:31

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PT. REPORTS SEEN BY  
DERMATOLOGIST FOR  
ROUTINE CHECK UP AND  
NOTED TO HAVE SUSPICIOUS  
MOLE ON BACK. EXCISED.  
BIOPSY POSITIVE FOR  
MELANOMA, AWAITING FULL  
PATHOLOGY REPORT. PATIENT  
REPORTS, HISTORY OF  
MELANOMA X2, NOT  
REPORTED AT SCREENING, 2011  
AND 2019.

BIOPSY 04SEP2020  
DIAGNOSIS MELANOMA  
09SEP2020  
EXCISED 21SEP2020  
AWAITING PATHOLOGY.

---

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)	

---

---



US3112121

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:20:36

Generated On: 09 Jun 2021 15:11:31

AEID

Adverse event

SURGICAL SITE INFECTION

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)

21 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)

28 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:20:36

Generated On: 09 Jun 2021 15:11:31

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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)	_____

US3112121

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Mar 2021 20:20:36

Generated On: 09 Jun 2021 15:11:31

AEID

Adverse event

VIRAL ILLNESS

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)

03 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)

06 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Mar 2021 20:20:36

Generated On: 09 Jun 2021 15:11:31

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

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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.

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US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU VACCINE

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 (1)

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication SURGICAL SITE INFECTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

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

US3112121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3112121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 21:00:46

Generated On: 09 Jun 2021 15:11:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 SEP 2020	MELANOMA EXCISED	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:11:31

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

US3112121

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:11:31

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 ☐

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

SAEID	USA-US062-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

SAEID	USA-US062-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

SAEID	USA-US062-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/OCT/2020 12:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 21:00:47

Generated On: 09 Jun 2021 15:11:31

SAEID	USA-US062-2020-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	28/OCT/2020 13:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3112121 (Prod: Medical Center For Clinical Research - M3 Wake Research)

**US3112121**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:11:31**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'US3112121'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:04:13

**US3112121**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	06 Aug 2020 00:30:42

**US3112121**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:04:14

**US3112121**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	06 Aug 2020 00:30:42

**US3112121**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'SCRN'	System	06 Aug 2020 00:30:42

US3112121

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered (b) (6) 1966'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:04:15



**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '54'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'YEARS'	System	12 Aug 2020 20:44:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '54'	System	06 Aug 2020 00:30:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Male (M)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'I'	Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52



US3112121

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

US3112121

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered empty.	(b) (4) Matthew Musikanth	12 Aug 2020 20:44:52
	(b) (4)	

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

**US3112121**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:11:31**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:44:52

US3112121

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '5 Aug 2020'	(b) (4) Matthew Musikanth (b) (4)	06 Aug 2020 00:30:52

**US3112121**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Aug 2020'	System	06 Aug 2020 00:30:52



**US3112121**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '2020'	System	06 Aug 2020 00:30:52

**US3112121**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:11:31**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Amendment 1 (1)'	(b) (4) Matthew Musikanth (b) (4)	06 Aug 2020 00:30:52

US3112121

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	06 Aug 2020 00:30:52

**US3112121**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered empty.	(b) (4) Matthew Musikanth	06 Aug 2020 00:30:52
	(b) (4)	

US3112121

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered empty.	(b) (4) Matthew Musikanth	06 Aug 2020 00:30:52
	(b) (4)	

**US3112121**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:11:31**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	06 Aug 2020 00:30:52

US3112121

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:04:14

**US3112121**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:11:31**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'I'	System	06 Aug 2020 00:30:56



US3112121

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	06 Aug 2020 00:30:56

US3112121

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:11:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	05 Sep 2020 20:38:33
User entered 'No (N)'	(b) (4)	
	Matthew Musikanth	12 Aug 2020 20:44:59
	(b) (4)	

US3112121

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
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)	05 Sep 2020 20:39:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 20:39:43
Data point term sent to Coder	System	05 Sep 2020 20:39:25
User entered 'Seasonal allergies'	Karen Mylerberg (b) (4)	05 Sep 2020 20:38:52

**US3112121**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'UN UNK 1976'	Karen Mylerberg (b) (4)	05 Sep 2020 20:38:52

**US3112121**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:38:52

**US3112121**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:38:52

**US3112121**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 20:38:52

**US3112121**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 20:38:52



**US3112121**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Jan 1976'	System	05 Sep 2020 20:38:52

**US3112121**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '1976'	System	05 Sep 2020 20:38:52

**US3112121**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered empty.	System	05 Sep 2020 20:38:52

**US3112121**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered empty.	System	05 Sep 2020 20:38:52

US3112121

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:50:49
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:16:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:16:37
Data point term sent to Coder	System	19 Oct 2020 20:20:57
User entered 'melanoma (abd)'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:20:47

US3112121

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:50:49
User closed query 'Please clarify. Per medical records received, med hx of 12/2010. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:50:36
Query 'Please clarify. Per medical records received, med hx of 12/2010. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	29 Oct 2020 20:49:29
User entered 'UN Dec 2010' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 20:49:21
User opened query 'Please clarify. Per medical records received, med hx of 12/2010. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:48:51
User entered 'un UNK 2011'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:20:47

**US3112121**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:50:49
User entered '0'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:20:47

**US3112121**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:50:49
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:20:47



US3112121

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:50:49
User entered 'UN Dec 2010' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 20:49:43
User entered 'un UNK 2011'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:20:47

**US3112121**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:50:49
User entered '0'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:20:47

**US3112121**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Dec 2010'	System	29 Oct 2020 20:49:21
User entered 'Jan 2011'	System	19 Oct 2020 20:20:47

**US3112121**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '2010'	System	29 Oct 2020 20:49:21
User entered '2011'	System	19 Oct 2020 20:20:47

**US3112121**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Dec 2010'	System	29 Oct 2020 20:49:43
User entered 'Jan 2011'	System	19 Oct 2020 20:20:47

**US3112121**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '2010'	System	29 Oct 2020 20:49:43
User entered '2011'	System	19 Oct 2020 20:20:47

US3112121

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:07:45
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:16:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:16:37
Data point term sent to Coder	System	19 Oct 2020 20:21:58
User entered 'melanoma (left bicep)'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:21:11

US3112121

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:07:45
User entered '20 Nov 2019' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 20:55:38
User entered 'un UNK 2019'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:21:11



**US3112121**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:07:45
User entered '0'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:21:11

**US3112121**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:07:45
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:21:11

US3112121

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	09 Nov 2020 23:29:27
User entered '20 Nov 2019' reason for change: Data Entry Error	Natalie Moy (b) (4)	09 Nov 2020 23:29:27
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	09 Nov 2020 23:29:10
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	09 Nov 2020 23:29:10
DataPoint Un-verified.	Natalie Moy (b) (4)	09 Nov 2020 23:29:10
User entered 'UN Nov 2019' reason for change: Data Entry Error	Natalie Moy (b) (4)	09 Nov 2020 23:29:10
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:07:45
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	29 Oct 2020 20:55:38
User entered 'un UNK 2019'	Natalie Moy (b) (4)	19 Oct 2020 20:21:11

**US3112121**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:07:45
User entered '0'	Natalie Moy (b) (4) (b) (4)	19 Oct 2020 20:21:11

**US3112121**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Nov 2019'	System	29 Oct 2020 20:55:38
User entered 'Jan 2019'	System	19 Oct 2020 20:21:11

**US3112121**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '2019'	System	19 Oct 2020 20:21:11

**US3112121**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Nov 2019'	System	09 Nov 2020 23:29:10
User entered 'Jan 2019'	System	19 Oct 2020 20:21:11

**US3112121**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '2019'	System	19 Oct 2020 20:21:11



US3112121

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip surgery, LLT: Hip surgery - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 07:02:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 07:02:42
Data point term sent to Coder	System	19 Oct 2020 20:25:01
User entered 'hip repair, torn labrum' reason for change: Data Entry Error	Natalie Moy (b) (4)	19 Oct 2020 20:24:29
Data point term sent to Coder	System	19 Oct 2020 20:24:00
User entered 'nevus back melanoma biopsy'	Natalie Moy (b) (4)	19 Oct 2020 20:23:51

US3112121

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	19 Oct 2020 20:24:29
User entered 'un Dec 2017' reason for change: Data Entry Error	Natalie Moy (b) (4)	19 Oct 2020 20:24:29
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	19 Oct 2020 20:23:51
User entered '9 Sep 2020'	Natalie Moy (b) (4)	19 Oct 2020 20:23:51

**US3112121**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:11:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Natalie Moy (b) (4)	19 Oct 2020 20:23:51

**US3112121**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:11:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	Natalie Moy (b) (4)	19 Oct 2020 20:23:51

US3112121

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'un Dec 2017' reason for change: Data Entry Error	(b) (4)	
	Natalie Moy (b) (4)	19 Oct 2020 20:24:29
User entered '1 Oct 2020'	(b) (4)	
	Natalie Moy (b) (4)	19 Oct 2020 20:23:51
	(b) (4)	

**US3112121**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:11:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Natalie Moy (b) (4)	19 Oct 2020 20:23:51

**US3112121**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Dec 2017'	System	19 Oct 2020 20:24:29
User entered 'Sep 2020'	System	19 Oct 2020 20:23:51

**US3112121**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '2017'	System	19 Oct 2020 20:24:29
User entered '2020'	System	19 Oct 2020 20:23:51



**US3112121**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Dec 2017'	System	19 Oct 2020 20:24:29
User entered 'Oct 2020'	System	19 Oct 2020 20:23:51

**US3112121**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '2017'	System	19 Oct 2020 20:24:29
User entered '2020'	System	19 Oct 2020 20:23:51

US3112121

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone operation, LLT: Bone operation - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 12:48:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 12:48:55
Data point term sent to Coder	System	10 Dec 2020 18:05:49
User closed query 'CDM Coding, please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Pelvic operation, Bone operation etc). ' (Site from System).	System	10 Dec 2020 18:05:37
Query 'CDM Coding, please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Pelvic operation, Bone operation etc). ' answered with 'TRANSCRIPTION ERROR' (Site from System).	Brenda Grande (b) (4)	10 Dec 2020 18:05:37
User entered 'PUBIS RESECTION' reason for change: Data Entry Error	Brenda Grande (b) (4)	10 Dec 2020 18:05:22
User opened query 'CDM Coding, please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Pelvic operation, Bone operation etc). ' (Site from System).	Coder Import (b) (4)	25 Nov 2020 05:34:02
Data point term sent to Coder	System	19 Oct 2020 20:26:02
User entered 'pubic resection'	Natalie Moy (b) (4)	19 Oct 2020 20:25:03

**US3112121**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'un Dec 2017'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 20:25:03

**US3112121**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Natalie Moy (b) (4)	19 Oct 2020 20:25:03

**US3112121**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 20:25:03

**US3112121**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'un Dec 2017'	(b) (4) Natalie Moy (b) (4)	19 Oct 2020 20:25:03

**US3112121**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Natalie Moy (b) (4)	19 Oct 2020 20:25:03



**US3112121**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Dec 2017'	System	19 Oct 2020 20:25:03

**US3112121**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '2017'	System	19 Oct 2020 20:25:03

**US3112121**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'Dec 2017'	System	19 Oct 2020 20:25:03

**US3112121**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '2017'	System	19 Oct 2020 20:25:03

**US3112121**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:45:57

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '05 Aug 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:45:57

**US3112121**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '15:47'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:45:57

**US3112121**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered '05 Aug 2020 15:47'	System	12 Aug 2020 20:45:57



US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '68' in	(b) (4)	12 Aug 2020 20:45:57
DataPoint set to visible.	Matthew Musikanth (b) (4)	06 Aug 2020 00:30:56
	System	

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '167' lb	(b) (4)	12 Aug 2020 20:45:57
DataPoint set to visible.	Matthew Musikanth (b) (4)	06 Aug 2020 00:30:56
	System	

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
Amendment Manager: User entered '25.44536'	System	16 Sep 2020 23:44:51
User entered '25.4'	System	12 Aug 2020 20:45:57
DataPoint set to visible.	System	06 Aug 2020 00:30:56

**US3112121**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'kg/m2'	System	12 Aug 2020 20:45:57
DataPoint set to visible.	System	06 Aug 2020 00:30:56

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 03:45:08
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Updated ' (Site from DM).	Karen Mylerberg (b) (4)	05 Sep 2020 04:33:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:33:26
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 19:21:45
User entered '98.5' F	Matthew Musikanth (b) (4)	12 Aug 2020 20:45:57

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered empty; reason for change Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	05 Sep 2020 04:33:26
User entered 'Oral (Oral)'	(b) (4)	
	Matthew Musikanth	12 Aug 2020 20:45:57
	(b) (4)	

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:45:57

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:33:26
User entered '49'	Karen Mylerberg (b) (4)	12 Aug 2020 20:45:57
	Matthew Musikanth (b) (4)	



**US3112121**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'bpm'	System	12 Aug 2020 20:45:57

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:33:26
User entered '16'	Matthew Musikanth (b) (4)	12 Aug 2020 20:45:57

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'breaths/min'	System	12 Aug 2020 20:45:57

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:33:26
User entered '135'	Matthew Musikanth (b) (4)	12 Aug 2020 20:45:57

**US3112121**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'mmHg'	System	12 Aug 2020 20:45:57

US3112121

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 04:33:26
User entered '83'	Matthew Musikanth (b) (4)	12 Aug 2020 20:45:57

**US3112121**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User entered 'mmHg'	System	12 Aug 2020 20:45:57

**US3112121**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05



**US3112121**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05

US3112121

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:45:08

US3112121

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:48:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 22:43:32
User entered '05 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 20:45:08

US3112121

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

US3112121

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

US3112121

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

**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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

US3112121

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32



US3112121

Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

US3112121

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

**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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

US3112121

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

[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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

**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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

**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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

**US3112121**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:11:31**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32



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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

US3112121

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

**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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

[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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

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)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

US3112121

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'I'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

**US3112121**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:11:31**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered 'I'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 20:46:32

US3112121

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:57:05
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:46:07
User entered '4-5 member family'	(b) (4) Matthew Musikanth	12 Aug 2020 20:46:32
	(b) (4)	



**US3112121**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:42

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '05 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:42

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:42

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'VISIT1'	System	12 Aug 2020 20:46:42

US3112121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:09:09

US3112121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:24:40
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:24:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 23:09:09
User entered '101433' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:09:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:09:09

US3112121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:31

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:51



US3112121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:31

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:51

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:51

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:11:31**

**Diabetes (Type I, Type 2, or gestational)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:51

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:11:31**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:51

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	



US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '05 Aug 2020'	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	

**US3112121**

**Folder: Visit 1 Day 1**

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

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '15:47'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

**US3112121**

**Folder: Visit 1 Day 1**

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

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '05 Aug 2020 15:47'	System	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '98.5' F	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Oral (Oral)'	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	



US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '49'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'bpm'	System	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'breaths/min'	System	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '135'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '83'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	12 Aug 2020 21:12:45



US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered missing code ND - Not Done.	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '05 Aug 2020'	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4)	18 Aug 2020 16:23:56
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		12 Aug 2020 21:12:45
User entered '17:27'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

**US3112121**

**Folder: Visit 1 Day 1**

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

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '05 Aug 2020 17:27'	System	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '97.5' F	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Oral (Oral)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '56'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'bpm'	System	12 Aug 2020 21:12:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'breaths/min'	System	12 Aug 2020 21:12:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '142'	(b) (4) Matthew Musikanth	12 Aug 2020 21:12:45
	(b) (4)	

**US3112121**

**Folder: Visit 1 Day 1**

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

**Generated On: 09 Jun 2021 15:11:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	12 Aug 2020 21:12:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '82'	Matthew Musikanth (b) (4)	12 Aug 2020 21:12:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	12 Aug 2020 21:12:45

US3112121

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:59

US3112121

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '05 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 20:46:59

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Aug 2020 00:31:13

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	(b) (4) Matthew Musikanth	06 Aug 2020 00:31:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	Matthew Musikanth (b) (4)	06 Aug 2020 00:31:13

US3112121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 00:31:13



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '5 Aug 2020'	Matthew Musikanth (b) (4)	06 Aug 2020 00:31:13

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16:50'	Matthew Musikanth (b) (4)	06 Aug 2020 00:31:13

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '5 Aug 2020 16:50'	System	06 Aug 2020 00:31:13

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	06 Aug 2020 00:31:13

US3112121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'ONCE'	System	06 Aug 2020 00:31:13

US3112121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 00:31:13

US3112121

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 21:13:00

US3112121

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '05 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 21:13:00



**US3112121**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:11:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16:06'	Matthew Musikanth (b) (4)	12 Aug 2020 21:13:00

US3112121

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '05 Aug 2020 16:06'	System	12 Aug 2020 21:13:00

US3112121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:11:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '05 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 21:13:10

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Matthew Musikanth (b) (4)	12 Aug 2020 21:13:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	12 Aug 2020 21:13:10
	(b) (4)	

US3112121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16:01'	(b) (4) Matthew Musikanth	12 Aug 2020 21:13:10
	(b) (4)	

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '05 Aug 2020 16:01'	System	12 Aug 2020 21:13:10

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Matthew Musikanth (b) (4)	12 Aug 2020 21:13:10



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'No (N)'	(b) (4) Matthew Musikanth	12 Aug 2020 21:13:10
	(b) (4)	

US3112121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 21:13:10

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered empty.	System	12 Aug 2020 21:13:10

US3112121

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 21:13:14

**US3112121**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'I'	System	12 Aug 2020 21:13:14

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:31:57', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '980938c1-d07d-473b-8b9d-8a7f3b6cc626'	System	06 Aug 2020 00:32:18
User entered 'Yes (Y)'	System	06 Aug 2020 00:32:18

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:32:06', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '980938c1-d07d-473b-8b9d-8a7f3b6cc626' User entered '97.5'	System	06 Aug 2020 00:32:18
	System	06 Aug 2020 00:32:18



US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:32:11', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '980938c1-d07d-473b-8b9d-8a7f3b6cc626'	System	06 Aug 2020 00:32:18
User entered 'No (N)'	System	06 Aug 2020 00:32:18

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:32:16', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '980938c1-d07d-473b-8b9d-8a7f3b6cc626' User entered '05 Aug 2020 17:32'	System	06 Aug 2020 00:32:18
	System	06 Aug 2020 00:32:18

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Aug 2020 17:10'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Aug 2020 19:40'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:11:03', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f8dec8e0-9db8-44a7-89b5-321929980214' User entered 'Yes (Y)'	System	06 Aug 2020 06:11:37
	System	06 Aug 2020 06:11:37

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:11:27', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f8dec8e0-9db8-44a7-89b5-321929980214' User entered '97.9'	System	06 Aug 2020 06:11:37
	System	06 Aug 2020 06:11:37

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:11:30', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f8dec8e0-9db8-44a7-89b5-321929980214' User entered 'No (N)'	System	06 Aug 2020 06:11:37
	System	06 Aug 2020 06:11:37



**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:11:35', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f8dec8e0-9db8-44a7-89b5-321929980214' User entered '05 Aug 2020 23:11'	System	06 Aug 2020 06:11:37
	System	06 Aug 2020 06:11:37

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Aug 2020 20:35'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 2'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:18:02', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a252b19a-84a4-411f-9056-72bc7190b59f' User entered 'Yes (Y)'	System	07 Aug 2020 01:18:15
	System	07 Aug 2020 01:18:15

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:18:06', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a252b19a-84a4-411f-9056-72bc7190b59f' User entered '97.9'	System	07 Aug 2020 01:18:15
	System	07 Aug 2020 01:18:15

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:18:09', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a252b19a-84a4-411f-9056-72bc7190b59f' User entered 'No (N)'	System	07 Aug 2020 01:18:15
	System	07 Aug 2020 01:18:15

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:18:14', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a252b19a-84a4-411f-9056-72bc7190b59f' User entered '06 Aug 2020 18:18'	System	07 Aug 2020 01:18:15
	System	07 Aug 2020 01:18:15



US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 3'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:21', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a436dd1d-5076-4b74-81bf-f97cd634c166'	System	07 Aug 2020 19:01:37
User entered 'Yes (Y)'	System	07 Aug 2020 19:01:37

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a436dd1d-5076-4b74-81bf-f97cd634c166' User entered '97.9'	System	07 Aug 2020 19:01:37
	System	07 Aug 2020 19:01:37

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a436dd1d-5076-4b74-81bf-f97cd634c166'	System	07 Aug 2020 19:01:37
User entered 'No (N)'	System	07 Aug 2020 19:01:37

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:31', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a436dd1d-5076-4b74-81bf-f97cd634c166'	System	07 Aug 2020 19:01:37
User entered '07 Aug 2020 12:01'	System	07 Aug 2020 19:01:37

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 00:31:13



US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 4'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:37:12', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0dd8301b-c19a-4664-8c50-3350b9877819'	System	08 Aug 2020 22:37:28
User entered 'Yes (Y)'	System	08 Aug 2020 22:37:28

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:37:18', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0dd8301b-c19a-4664-8c50-3350b9877819' User entered '98.7'	System	08 Aug 2020 22:37:28
	System	08 Aug 2020 22:37:28

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:37:21', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0dd8301b-c19a-4664-8c50-3350b9877819'	System	08 Aug 2020 22:37:28
User entered 'No (N)'	System	08 Aug 2020 22:37:28

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:37:23', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0dd8301b-c19a-4664-8c50-3350b9877819' User entered '08 Aug 2020 15:37'	System	08 Aug 2020 22:37:28
	System	08 Aug 2020 22:37:28

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 00:31:13



US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 5'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:02:41', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '7c0cfd0b-7003-462a-b9ba-28feb9d14f91'	System	10 Aug 2020 07:03:00
User entered 'Yes (Y)'	System	10 Aug 2020 07:03:00

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:02:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '7c0cfd0b-7003-462a-b9ba-28feb9d14f91' User entered '97.5'	System	10 Aug 2020 07:03:00
	System	10 Aug 2020 07:03:00

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:02:55', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '7c0cfd0b-7003-462a-b9ba-28feb9d14f91'	System	10 Aug 2020 07:03:00
User entered 'No (N)'	System	10 Aug 2020 07:03:00

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:02:58', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '7c0cfd0b-7003-462a-b9ba-28feb9d14f91' User entered '10 Aug 2020 00:02'	System	10 Aug 2020 07:03:00
	System	10 Aug 2020 07:03:00

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 6'	System	06 Aug 2020 00:31:13



US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:40:50', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4115e417-2fc6-4522-9072-530a16cad2a1' User entered 'Yes (Y)'	System	11 Aug 2020 16:41:03
	System	11 Aug 2020 16:41:03

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:40:53', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4115e417-2fc6-4522-9072-530a16cad2a1' User entered '97.6'	System	11 Aug 2020 16:41:03
	System	11 Aug 2020 16:41:03

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:40:57', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4115e417-2fc6-4522-9072-530a16cad2a1'	System	11 Aug 2020 16:41:03
User entered 'No (N)'	System	11 Aug 2020 16:41:03

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4115e417-2fc6-4522-9072-530a16cad2a1' User entered '11 Aug 2020 09:41'	System	11 Aug 2020 16:41:03
	System	11 Aug 2020 16:41:03

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 7'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:24:22', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '869b54a8-b9e1-4162-a5fc-6e7a6d4ca940'	System	12 Aug 2020 17:24:43
User entered 'Yes (Y)'	System	12 Aug 2020 17:24:43



US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:24:26', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '869b54a8-b9e1-4162-a5fc-6e7a6d4ca940' User entered '97.6'	System	12 Aug 2020 17:24:43
	System	12 Aug 2020 17:24:43

US3112121

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:24:37', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '869b54a8-b9e1-4162-a5fc-6e7a6d4ca940'	System	12 Aug 2020 17:24:43
User entered 'No (N)'	System	12 Aug 2020 17:24:43

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:24:41', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '869b54a8-b9e1-4162-a5fc-6e7a6d4ca940' User entered '12 Aug 2020 10:24'	System	12 Aug 2020 17:24:43
	System	12 Aug 2020 17:24:43

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:32:35', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3b0edb5e-04b9-4337-af40-3114fecbb096'	System	06 Aug 2020 00:33:09
User entered 'None (1)'	System	06 Aug 2020 00:33:09

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:32:46', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3b0edb5e-04b9-4337-af40-3114fecbb096'	System	06 Aug 2020 00:33:09
User entered 'No (N)'	System	06 Aug 2020 00:33:09



US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:32:50', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3b0edb5e-04b9-4337-af40-3114fecbb096'	System	06 Aug 2020 00:33:09
User entered 'No (N)'	System	06 Aug 2020 00:33:09

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:01', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3b0edb5e-04b9-4337-af40-3114fecbb096'	System	06 Aug 2020 00:33:09
User entered 'None (1)'	System	06 Aug 2020 00:33:09

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:05', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3b0edb5e-04b9-4337-af40-3114fecbb096'	System	06 Aug 2020 00:33:09
User entered '05 Aug 2020 17:33'	System	06 Aug 2020 00:33:09

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Aug 2020 17:10'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Aug 2020 19:40'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:11:59', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ac32bcd6-c015-4e79-8e5f-a469cc7a62d6'	System	06 Aug 2020 06:12:23
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 06:12:23

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:02', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ac32bcd6-c015-4e79-8e5f-a469cc7a62d6'	System	06 Aug 2020 06:12:23
User entered 'No (N)'	System	06 Aug 2020 06:12:23



US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:11', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ac32bcd6-c015-4e79-8e5f-a469cc7a62d6'	System	06 Aug 2020 06:12:23
User entered 'No (N)'	System	06 Aug 2020 06:12:23

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:16', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ac32bcd6-c015-4e79-8e5f-a469cc7a62d6'	System	06 Aug 2020 06:12:23
User entered 'None (1)'	System	06 Aug 2020 06:12:23

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:19', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ac32bcd6-c015-4e79-8e5f-a469cc7a62d6'	System	06 Aug 2020 06:12:23
User entered '05 Aug 2020 23:12'	System	06 Aug 2020 06:12:23

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Aug 2020 20:35'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 2'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:18:29', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '27fe4b8a-6563-4c0f-95f5-20e230d66cc0'	System	07 Aug 2020 01:19:11
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 01:19:11

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:18:54', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '27fe4b8a-6563-4c0f-95f5-20e230d66cc0' User entered 'No (N)'	System	07 Aug 2020 01:19:11
	System	07 Aug 2020 01:19:11



US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:18:58', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '27fe4b8a-6563-4c0f-95f5-20e230d66cc0'	System	07 Aug 2020 01:19:11
User entered 'No (N)'	System	07 Aug 2020 01:19:11

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:04', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '27fe4b8a-6563-4c0f-95f5-20e230d66cc0' User entered 'None (1)'	System	07 Aug 2020 01:19:11
	System	07 Aug 2020 01:19:11

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:09', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '27fe4b8a-6563-4c0f-95f5-20e230d66cc0' User entered '06 Aug 2020 18:19'	System	07 Aug 2020 01:19:11
	System	07 Aug 2020 01:19:11

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 3'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:39', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd560f7f2-5987-4d2c-b121-e140379c3a73'	System	07 Aug 2020 19:01:57
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 19:01:57

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:43', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd560f7f2-5987-4d2c-b121-e140379c3a73'	System	07 Aug 2020 19:01:57
User entered 'No (N)'	System	07 Aug 2020 19:01:57



US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:46', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd560f7f2-5987-4d2c-b121-e140379c3a73'	System	07 Aug 2020 19:01:57
User entered 'No (N)'	System	07 Aug 2020 19:01:57

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:51', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd560f7f2-5987-4d2c-b121-e140379c3a73'	System	07 Aug 2020 19:01:57
User entered 'None (1)'	System	07 Aug 2020 19:01:57

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:53', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd560f7f2-5987-4d2c-b121-e140379c3a73'	System	07 Aug 2020 19:01:57
User entered '07 Aug 2020 12:01'	System	07 Aug 2020 19:01:57

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 4'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:37:38', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a8b23386-1b95-4495-9909-cb7b33a8d1e7'	System	08 Aug 2020 22:38:10
User entered 'None (1)'	System	08 Aug 2020 22:38:10

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:37:41', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a8b23386-1b95-4495-9909-cb7b33a8d1e7'	System	08 Aug 2020 22:38:10
User entered 'No (N)'	System	08 Aug 2020 22:38:10



US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:37:56', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a8b23386-1b95-4495-9909-cb7b33a8d1e7'	System	08 Aug 2020 22:38:10
User entered 'No (N)'	System	08 Aug 2020 22:38:10

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:04', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a8b23386-1b95-4495-9909-cb7b33a8d1e7'	System	08 Aug 2020 22:38:10
User entered 'None (1)'	System	08 Aug 2020 22:38:10

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:07', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a8b23386-1b95-4495-9909-cb7b33a8d1e7'	System	08 Aug 2020 22:38:10
User entered '08 Aug 2020 15:38'	System	08 Aug 2020 22:38:10

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 5'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:24', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ed7e2a4e-feaf-4930-9a86-f3cad1fb89a4'	System	10 Aug 2020 07:03:39
User entered 'None (1)'	System	10 Aug 2020 07:03:39

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:27', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ed7e2a4e-feaf-4930-9a86-f3cad1fb89a4'	System	10 Aug 2020 07:03:39
User entered 'No (N)'	System	10 Aug 2020 07:03:39



US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:29', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ed7e2a4e-feaf-4930-9a86-f3cad1fb89a4' User entered 'No (N)'	System	10 Aug 2020 07:03:39
	System	10 Aug 2020 07:03:39

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:31', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ed7e2a4e-feaf-4930-9a86-f3cad1fb89a4'	System	10 Aug 2020 07:03:39
User entered 'None (1)'	System	10 Aug 2020 07:03:39

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:34', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'ed7e2a4e-feaf-4930-9a86-f3cad1fb89a4' User entered '10 Aug 2020 00:03'	System	10 Aug 2020 07:03:39
	System	10 Aug 2020 07:03:39

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 6'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:04', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '1f839e18-27c0-4eb8-a533-f0ae4935b2ee'	System	11 Aug 2020 16:41:15
User entered 'None (1)'	System	11 Aug 2020 16:41:15

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:06', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '1f839e18-27c0-4eb8-a533-f0ae4935b2ee'	System	11 Aug 2020 16:41:15
User entered 'No (N)'	System	11 Aug 2020 16:41:15



US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:08', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '1f839e18-27c0-4eb8-a533-f0ae4935b2ee'	System	11 Aug 2020 16:41:15
User entered 'No (N)'	System	11 Aug 2020 16:41:15

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:11', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '1f839e18-27c0-4eb8-a533-f0ae4935b2ee'	System	11 Aug 2020 16:41:15
User entered 'None (1)'	System	11 Aug 2020 16:41:15

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:13', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '1f839e18-27c0-4eb8-a533-f0ae4935b2ee' User entered '11 Aug 2020 09:41'	System	11 Aug 2020 16:41:15
	System	11 Aug 2020 16:41:15

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 7'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:24:45', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'cf6f25a2-2756-4424-bcc9-96bbf0948cae'	System	12 Aug 2020 17:25:43
User entered 'None (1)'	System	12 Aug 2020 17:25:43

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:24:57', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'cf6f25a2-2756-4424-bcc9-96bbf0948cae'	System	12 Aug 2020 17:25:43
User entered 'No (N)'	System	12 Aug 2020 17:25:43



US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:24:59', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'cf6f25a2-2756-4424-bcc9-96bbf0948cae'	System	12 Aug 2020 17:25:43
User entered 'No (N)'	System	12 Aug 2020 17:25:43

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:25:02', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'cf6f25a2-2756-4424-bcc9-96bbf0948cae'	System	12 Aug 2020 17:25:43
User entered 'None (1)'	System	12 Aug 2020 17:25:43

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:25:41', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'cf6f25a2-2756-4424-bcc9-96bbf0948cae' User entered '12 Aug 2020 10:25'	System	12 Aug 2020 17:25:43
	System	12 Aug 2020 17:25:43

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:20', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fc6c904d-fd73-45c2-b71b-2aa33929c1bd' User entered 'None (0)'	System	06 Aug 2020 00:34:03
	System	06 Aug 2020 00:34:03

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:26', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fc6c904d-fd73-45c2-b71b-2aa33929c1bd' User entered 'None (0)'	System	06 Aug 2020 00:34:03
	System	06 Aug 2020 00:34:03



**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:30', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fc6c904d-fd73-45c2-b71b-2aa33929c1bd' User entered 'None (0)'	System	06 Aug 2020 00:34:03
	System	06 Aug 2020 00:34:03

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:32', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fc6c904d-fd73-45c2-b71b-2aa33929c1bd' User entered 'None (0)'	System	06 Aug 2020 00:34:03
	System	06 Aug 2020 00:34:03

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:44', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fc6c904d-fd73-45c2-b71b-2aa33929c1bd' User entered 'None (0)'	System	06 Aug 2020 00:34:03
	System	06 Aug 2020 00:34:03

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:47', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fc6c904d-fd73-45c2-b71b-2aa33929c1bd' User entered 'None (0)'	System	06 Aug 2020 00:34:03
	System	06 Aug 2020 00:34:03

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:55', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fc6c904d-fd73-45c2-b71b-2aa33929c1bd' User entered 'No (N)'	System	06 Aug 2020 00:34:03
	System	06 Aug 2020 00:34:03

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T17:33:59', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fc6c904d-fd73-45c2-b71b-2aa33929c1bd' User entered '05 Aug 2020 17:33'	System	06 Aug 2020 00:34:03
	System	06 Aug 2020 00:34:03

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Aug 2020 17:10'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Aug 2020 19:40'	System	06 Aug 2020 00:31:13



US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:27', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e051600a-1b2d-4206-bb9e-d0f3af63d17f' User entered 'None (0)'	System	06 Aug 2020 06:12:55
	System	06 Aug 2020 06:12:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:32', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e051600a-1b2d-4206-bb9e-d0f3af63d17f' User entered 'None (0)'	System	06 Aug 2020 06:12:55
	System	06 Aug 2020 06:12:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:35', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e051600a-1b2d-4206-bb9e-d0f3af63d17f' User entered 'None (0)'	System	06 Aug 2020 06:12:55
	System	06 Aug 2020 06:12:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:38', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e051600a-1b2d-4206-bb9e-d0f3af63d17f' User entered 'None (0)'	System	06 Aug 2020 06:12:55
	System	06 Aug 2020 06:12:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:41', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e051600a-1b2d-4206-bb9e-d0f3af63d17f' User entered 'None (0)'	System	06 Aug 2020 06:12:55
	System	06 Aug 2020 06:12:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:43', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e051600a-1b2d-4206-bb9e-d0f3af63d17f' User entered 'None (0)'	System	06 Aug 2020 06:12:55
	System	06 Aug 2020 06:12:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:47', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e051600a-1b2d-4206-bb9e-d0f3af63d17f' User entered 'No (N)'	System	06 Aug 2020 06:12:55
	System	06 Aug 2020 06:12:55



**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-05T23:12:50', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e051600a-1b2d-4206-bb9e-d0f3af63d17f' User entered '05 Aug 2020 23:12'	System	06 Aug 2020 06:12:55
	System	06 Aug 2020 06:12:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Aug 2020 20:35'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 2'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '23fccd31-7ec3-442d-8fc4-59777230b408'	System	07 Aug 2020 01:19:49
User entered 'No interference with activity (1)'	System	07 Aug 2020 01:19:49

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '23fccd31-7ec3-442d-8fc4-59777230b408'	System	07 Aug 2020 01:19:49
User entered 'None (0)'	System	07 Aug 2020 01:19:49

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:32', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '23fccd31-7ec3-442d-8fc4-59777230b408'	System	07 Aug 2020 01:19:49
User entered 'None (0)'	System	07 Aug 2020 01:19:49

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:34', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '23fccd31-7ec3-442d-8fc4-59777230b408'	System	07 Aug 2020 01:19:49
User entered 'None (0)'	System	07 Aug 2020 01:19:49



US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:37', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '23fccd31-7ec3-442d-8fc4-59777230b408'	System	07 Aug 2020 01:19:49
User entered 'None (0)'	System	07 Aug 2020 01:19:49

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:39', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '23fccd31-7ec3-442d-8fc4-59777230b408'	System	07 Aug 2020 01:19:49
User entered 'None (0)'	System	07 Aug 2020 01:19:49

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:43', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '23fccd31-7ec3-442d-8fc4-59777230b408'	System	07 Aug 2020 01:19:49
User entered 'No (N)'	System	07 Aug 2020 01:19:49

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-06T18:19:46', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '23fccd31-7ec3-442d-8fc4-59777230b408' User entered '06 Aug 2020 18:19'	System	07 Aug 2020 01:19:49
	System	07 Aug 2020 01:19:49

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 3'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:01:59', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '8662a96f-1be2-49b4-bbb6-713fcde031db'	System	07 Aug 2020 19:02:17
User entered 'No interference with activity (1)'	System	07 Aug 2020 19:02:17



US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:02:01', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '8662a96f-1be2-49b4-bbb6-713fcde031db' User entered 'None (0)'	System	07 Aug 2020 19:02:17
	System	07 Aug 2020 19:02:17

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:02:04', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '8662a96f-1be2-49b4-bbb6-713fcde031db' User entered 'None (0)'	System	07 Aug 2020 19:02:17
	System	07 Aug 2020 19:02:17

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:02:06', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '8662a96f-1be2-49b4-bbb6-713fcde031db' User entered 'None (0)'	System	07 Aug 2020 19:02:17
	System	07 Aug 2020 19:02:17

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:02:08', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '8662a96f-1be2-49b4-bbb6-713fcde031db' User entered 'None (0)'	System	07 Aug 2020 19:02:17
	System	07 Aug 2020 19:02:17

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:02:10', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '8662a96f-1be2-49b4-bbb6-713fcde031db' User entered 'None (0)'	System	07 Aug 2020 19:02:17
	System	07 Aug 2020 19:02:17

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:02:12', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '8662a96f-1be2-49b4-bbb6-713fcde031db' User entered 'No (N)'	System	07 Aug 2020 19:02:17
	System	07 Aug 2020 19:02:17

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-07T12:02:14', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '8662a96f-1be2-49b4-bbb6-713fcde031db' User entered '07 Aug 2020 12:02'	System	07 Aug 2020 19:02:17
	System	07 Aug 2020 19:02:17

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 00:31:13



**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 4'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:16', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4278c328-534c-4431-a32e-888a91a04a97'	System	08 Aug 2020 22:38:55
User entered 'None (0)'	System	08 Aug 2020 22:38:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:20', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4278c328-534c-4431-a32e-888a91a04a97'	System	08 Aug 2020 22:38:55
User entered 'None (0)'	System	08 Aug 2020 22:38:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:23', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4278c328-534c-4431-a32e-888a91a04a97' User entered 'None (0)'	System	08 Aug 2020 22:38:55
	System	08 Aug 2020 22:38:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4278c328-534c-4431-a32e-888a91a04a97'	System	08 Aug 2020 22:38:55
User entered 'None (0)'	System	08 Aug 2020 22:38:55

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4278c328-534c-4431-a32e-888a91a04a97' User entered 'None (0)'	System	08 Aug 2020 22:38:55
	System	08 Aug 2020 22:38:55

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:39', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4278c328-534c-4431-a32e-888a91a04a97'	System	08 Aug 2020 22:38:55
User entered 'None (0)'	System	08 Aug 2020 22:38:55



US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:45', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4278c328-534c-4431-a32e-888a91a04a97'	System	08 Aug 2020 22:38:55
User entered 'No (N)'	System	08 Aug 2020 22:38:55

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-08T15:38:48', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4278c328-534c-4431-a32e-888a91a04a97'	System	08 Aug 2020 22:38:55
User entered '08 Aug 2020 15:38'	System	08 Aug 2020 22:38:55

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 5'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:41', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0721a201-4db8-4fbd-8886-d201f357b82c' User entered 'None (0)'	System	10 Aug 2020 07:04:01
	System	10 Aug 2020 07:04:01

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:43', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0721a201-4db8-4fbd-8886-d201f357b82c' User entered 'None (0)'	System	10 Aug 2020 07:04:01
	System	10 Aug 2020 07:04:01

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:45', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0721a201-4db8-4fbd-8886-d201f357b82c' User entered 'None (0)'	System	10 Aug 2020 07:04:01
	System	10 Aug 2020 07:04:01



US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:47', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0721a201-4db8-4fbd-8886-d201f357b82c' User entered 'None (0)'	System	10 Aug 2020 07:04:01
	System	10 Aug 2020 07:04:01

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:49', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0721a201-4db8-4fbd-8886-d201f357b82c' User entered 'None (0)'	System	10 Aug 2020 07:04:01
	System	10 Aug 2020 07:04:01

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:51', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0721a201-4db8-4fbd-8886-d201f357b82c' User entered 'None (0)'	System	10 Aug 2020 07:04:01
	System	10 Aug 2020 07:04:01

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:56', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0721a201-4db8-4fbd-8886-d201f357b82c' User entered 'No (N)'	System	10 Aug 2020 07:04:01
	System	10 Aug 2020 07:04:01

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-10T00:03:59', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0721a201-4db8-4fbd-8886-d201f357b82c' User entered '10 Aug 2020 00:03'	System	10 Aug 2020 07:04:01
	System	10 Aug 2020 07:04:01

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 6'	System	06 Aug 2020 00:31:13



US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:18', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d8ad22e-d7f3-47a6-a1a8-710fff25b20e' User entered 'None (0)'	System	11 Aug 2020 16:41:35
	System	11 Aug 2020 16:41:35

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:21', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d8ad22e-d7f3-47a6-a1a8-710fff25b20e' User entered 'None (0)'	System	11 Aug 2020 16:41:35
	System	11 Aug 2020 16:41:35

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:23', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d8ad22e-d7f3-47a6-a1a8-710fff25b20e' User entered 'None (0)'	System	11 Aug 2020 16:41:35
	System	11 Aug 2020 16:41:35

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d8ad22e-d7f3-47a6-a1a8-710fff25b20e' User entered 'None (0)'	System	11 Aug 2020 16:41:35
	System	11 Aug 2020 16:41:35

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:26', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d8ad22e-d7f3-47a6-a1a8-710ff25b20e' User entered 'None (0)'	System	11 Aug 2020 16:41:35
	System	11 Aug 2020 16:41:35

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:29', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d8ad22e-d7f3-47a6-a1a8-710fff25b20e'	System	11 Aug 2020 16:41:35
User entered 'None (0)'	System	11 Aug 2020 16:41:35

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:32', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d8ad22e-d7f3-47a6-a1a8-710ff25b20e' User entered 'No (N)'	System	11 Aug 2020 16:41:35
	System	11 Aug 2020 16:41:35

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-11T09:41:33', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d8ad22e-d7f3-47a6-a1a8-710ff25b20e' User entered '11 Aug 2020 09:41'	System	11 Aug 2020 16:41:35
	System	11 Aug 2020 16:41:35



**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 7'	System	06 Aug 2020 00:31:13

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:25:50', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9135eae2-3360-454c-b34f-df56a0cfe6ba' User entered 'None (0)'	System	12 Aug 2020 17:26:10
	System	12 Aug 2020 17:26:10

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:25:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9135eae2-3360-454c-b34f-df56a0cfe6ba' User entered 'None (0)'	System	12 Aug 2020 17:26:10
	System	12 Aug 2020 17:26:10

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:25:55', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9135eae2-3360-454c-b34f-df56a0cfe6ba' User entered 'None (0)'	System	12 Aug 2020 17:26:10
	System	12 Aug 2020 17:26:10

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:25:56', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9135eae2-3360-454c-b34f-df56a0cfe6ba' User entered 'None (0)'	System	12 Aug 2020 17:26:10
	System	12 Aug 2020 17:26:10

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:25:58', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9135eae2-3360-454c-b34f-df56a0cfe6ba' User entered 'None (0)'	System	12 Aug 2020 17:26:10
	System	12 Aug 2020 17:26:10



US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:26:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9135eae2-3360-454c-b34f-df56a0cfe6ba' User entered 'None (0)'	System	12 Aug 2020 17:26:10
	System	12 Aug 2020 17:26:10

US3112121

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:26:04', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9135eae2-3360-454c-b34f-df56a0cfe6ba' User entered 'No (N)'	System	12 Aug 2020 17:26:10
	System	12 Aug 2020 17:26:10

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-08-12T10:26:06', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9135eae2-3360-454c-b34f-df56a0cfe6ba' User entered '12 Aug 2020 10:26'	System	12 Aug 2020 17:26:10
	System	12 Aug 2020 17:26:10

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	12 Aug 2020 21:20:00
	(b) (4)	

**US3112121**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered '12 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 21:20:00

**US3112121**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 21:20:00



**US3112121**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 21:20:00

US3112121

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	12 Aug 2020 21:20:04
	(b) (4)	

**US3112121**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'I'	System	12 Aug 2020 21:20:04

**US3112121**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	19 Aug 2020 23:49:56

US3112121

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	31 Aug 2020 21:35:40
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	31 Aug 2020 21:35:40
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	31 Aug 2020 21:35:40
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 21:35:40
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Aug 2020 23:49:56
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	19 Aug 2020 23:49:56
User entered '19 Apr 2020'	Matthew Musikanth (b) (4)	19 Aug 2020 23:49:56

**US3112121**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Musikanth (b) (4)	19 Aug 2020 23:49:56

**US3112121**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered empty.	(b) (4) Matthew Musikanth	19 Aug 2020 23:49:56
	(b) (4)	

**US3112121**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Aug 2020 23:50:01



**US3112121**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'I'	System	19 Aug 2020 23:50:01

**US3112121**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	26 Aug 2020 19:32:36
	(b) (4)	

**US3112121**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered '26 Aug 2020'	Matthew Musikanth (b) (4)	26 Aug 2020 19:32:36

**US3112121**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Musikanth (b) (4)	26 Aug 2020 19:32:36

**US3112121**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered empty.	Matthew Musikanth (b) (4)	26 Aug 2020 19:32:36

**US3112121**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Aug 2020 19:32:41

**US3112121**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'I'	System	26 Aug 2020 19:32:41

**US3112121**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:43:32



**US3112121**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:43:32

US3112121

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:43:32

**US3112121**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'VISIT2'	System	02 Sep 2020 22:43:32

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '2 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

**US3112121**

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

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

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '14:35'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

**US3112121**

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

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

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '2 Sep 2020 14:35'	System	05 Sep 2020 20:40:28



US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '98.2' F	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

**US3112121**

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

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

**Generated On: 09 Jun 2021 15:11:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '67'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

**US3112121**

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

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

**Generated On: 09 Jun 2021 15:11:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'bpm'	System	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'breaths/min'	System	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '118'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28



US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '088'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '2 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16:00'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

**US3112121**

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

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

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '2 Sep 2020 16:00'	System	05 Sep 2020 20:40:28



US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '98.6' F	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

**US3112121**

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

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

**Generated On: 09 Jun 2021 15:11:31**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '64'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'bpm'	System	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'breaths/min'	System	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '120'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28



**US3112121**

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

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

**Generated On: 09 Jun 2021 15:11:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '072'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	05 Sep 2020 20:40:28

US3112121

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	19 Oct 2020 14:50:55
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:37

US3112121

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 14:50:55
User entered empty.	(b) (4)	
	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:37
	(b) (4)	

US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:44:05

**US3112121**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 15:11:31**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:44:05

US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:44:05



US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 22:44:05

US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:44:05

US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '15:27'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:44:05

US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '2 Sep 2020 15:27'	System	02 Sep 2020 22:44:05

US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:44:05

US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'ONCE'	System	02 Sep 2020 22:44:05

US3112121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 22:44:05

US3112121

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:56



US3112121

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '2 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:56

**US3112121**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:11:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '14:45'	Karen Mylerberg (b) (4)	05 Sep 2020 20:40:56

**US3112121**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:11:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '2 Sep 2020 14:45'	System	05 Sep 2020 20:40:56

US3112121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:11:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '2 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 20:41:12

**US3112121**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:41:12

US3112121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:41:12

**US3112121**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:11:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '14:39'	Karen Mylerberg (b) (4)	05 Sep 2020 20:41:12

**US3112121**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '2 Sep 2020 14:39'	System	05 Sep 2020 20:41:12



**US3112121**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:41:12

US3112121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 20:41:12

**US3112121**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:11:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 20:41:12

**US3112121**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered empty.	System	05 Sep 2020 20:41:12

**US3112121**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 22:44:10

**US3112121**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'I'	System	02 Sep 2020 22:44:10

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:01:17', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9195c336-7405-409c-9b75-bcd35e9a2155'	System	02 Sep 2020 23:01:31
User entered 'Yes (Y)'	System	02 Sep 2020 23:01:31



US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:01:22', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9195c336-7405-409c-9b75-bcd35e9a2155' User entered '98.6'	System	02 Sep 2020 23:01:31
	System	02 Sep 2020 23:01:31

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:01:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9195c336-7405-409c-9b75-bcd35e9a2155'	System	02 Sep 2020 23:01:31
User entered 'No (N)'	System	02 Sep 2020 23:01:31

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:01:29', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9195c336-7405-409c-9b75-bcd35e9a2155'	System	02 Sep 2020 23:01:31
User entered '02 Sep 2020 16:01'	System	02 Sep 2020 23:01:31

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '02 Sep 2020 15:47'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '02 Sep 2020 18:17'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:26:27', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '64dcc658-3ed5-496f-89ef-534189cb8765'	System	03 Sep 2020 02:26:40
User entered 'Yes (Y)'	System	03 Sep 2020 02:26:40

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:26:31', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '64dcc658-3ed5-496f-89ef-534189cb8765' User entered '98.2'	System	03 Sep 2020 02:26:40
	System	03 Sep 2020 02:26:40



US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:26:34', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '64dcc658-3ed5-496f-89ef-534189cb8765'	System	03 Sep 2020 02:26:40
User entered 'No (N)'	System	03 Sep 2020 02:26:40

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:26:38', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '64dcc658-3ed5-496f-89ef-534189cb8765'	System	03 Sep 2020 02:26:40
User entered '02 Sep 2020 19:26'	System	03 Sep 2020 02:26:40

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '02 Sep 2020 19:12'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 2'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:14:46', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '917ef545-97ad-4e0f-8809-389e0ce95922'	System	04 Sep 2020 06:14:58
User entered 'Yes (Y)'	System	04 Sep 2020 06:14:58

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:14:50', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '917ef545-97ad-4e0f-8809-389e0ce95922' User entered '97.3'	System	04 Sep 2020 06:14:58
	System	04 Sep 2020 06:14:58

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:14:53', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '917ef545-97ad-4e0f-8809-389e0ce95922'	System	04 Sep 2020 06:14:58
User entered 'No (N)'	System	04 Sep 2020 06:14:58



US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:14:56', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '917ef545-97ad-4e0f-8809-389e0ce95922'	System	04 Sep 2020 06:14:58
User entered '03 Sep 2020 23:14'	System	04 Sep 2020 06:14:58

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 3'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:12', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd6314356-7218-46bc-bf0a-9ac0414fd652'	System	04 Sep 2020 19:02:26
User entered 'Yes (Y)'	System	04 Sep 2020 19:02:26

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:17', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd6314356-7218-46bc-bf0a-9ac0414fd652' User entered '97.8'	System	04 Sep 2020 19:02:26
	System	04 Sep 2020 19:02:26

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:19', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd6314356-7218-46bc-bf0a-9ac0414fd652'	System	04 Sep 2020 19:02:26
User entered 'No (N)'	System	04 Sep 2020 19:02:26

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:22', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd6314356-7218-46bc-bf0a-9ac0414fd652'	System	04 Sep 2020 19:02:26
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 19:02:26



US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 4'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:38:05', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '20f00593-c737-4fca-9807-b240195cdf41'	System	05 Sep 2020 23:39:47
User entered 'Yes (Y)'	System	05 Sep 2020 23:39:47

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:39:39', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '20f00593-c737-4fca-9807-b240195cdf41' User entered '98.7'	System	05 Sep 2020 23:39:47
	System	05 Sep 2020 23:39:47

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:39:41', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '20f00593-c737-4fca-9807-b240195cdf41'	System	05 Sep 2020 23:39:47
User entered 'No (N)'	System	05 Sep 2020 23:39:47

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:39:44', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '20f00593-c737-4fca-9807-b240195cdf41' User entered '05 Sep 2020 16:39'	System	05 Sep 2020 23:39:47
	System	05 Sep 2020 23:39:47

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:44:05



US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 5'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35



US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 6'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:05', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9b95e5e9-0c23-40d7-8d4d-bbb8d0f7a735'	System	07 Sep 2020 23:54:16
User entered 'Yes (Y)'	System	07 Sep 2020 23:54:16

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:08', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9b95e5e9-0c23-40d7-8d4d-bbb8d0f7a735' User entered '98.3'	System	07 Sep 2020 23:54:16
	System	07 Sep 2020 23:54:16

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:10', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9b95e5e9-0c23-40d7-8d4d-bbb8d0f7a735'	System	07 Sep 2020 23:54:16
User entered 'No (N)'	System	07 Sep 2020 23:54:16

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:14', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9b95e5e9-0c23-40d7-8d4d-bbb8d0f7a735' User entered '07 Sep 2020 16:54'	System	07 Sep 2020 23:54:16
	System	07 Sep 2020 23:54:16

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:44:05



US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 7'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9a3549ce-ea77-4572-b984-55bd69e7706b' User entered 'Yes (Y)'	System	08 Sep 2020 22:37:42
	System	08 Sep 2020 22:37:42

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:32', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9a3549ce-ea77-4572-b984-55bd69e7706b' User entered '97.8'	System	08 Sep 2020 22:37:42
	System	08 Sep 2020 22:37:42

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:35', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9a3549ce-ea77-4572-b984-55bd69e7706b' User entered 'No (N)'	System	08 Sep 2020 22:37:42
	System	08 Sep 2020 22:37:42

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:38', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9a3549ce-ea77-4572-b984-55bd69e7706b' User entered '08 Sep 2020 15:37'	System	08 Sep 2020 22:37:42
	System	08 Sep 2020 22:37:42

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:44:05



US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:02:16', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fd9b6036-4885-41c0-8743-0de29904ea9e' User entered 'None (1)'	System	02 Sep 2020 23:03:12
	System	02 Sep 2020 23:03:12

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:02:54', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fd9b6036-4885-41c0-8743-0de29904ea9e' User entered 'No (N)'	System	02 Sep 2020 23:03:12
	System	02 Sep 2020 23:03:12

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:03', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fd9b6036-4885-41c0-8743-0de29904ea9e' User entered 'No (N)'	System	02 Sep 2020 23:03:12
	System	02 Sep 2020 23:03:12

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:05', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fd9b6036-4885-41c0-8743-0de29904ea9e' User entered 'None (1)'	System	02 Sep 2020 23:03:12
	System	02 Sep 2020 23:03:12

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:08', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'fd9b6036-4885-41c0-8743-0de29904ea9e' User entered '02 Sep 2020 16:03'	System	02 Sep 2020 23:03:12
	System	02 Sep 2020 23:03:12

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '02 Sep 2020 15:47'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '02 Sep 2020 18:17'	System	02 Sep 2020 22:44:05



US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:26:57', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f29846d6-7e3b-4976-ac3d-72d43cd0111e'	System	03 Sep 2020 02:27:12
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 02:27:12

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f29846d6-7e3b-4976-ac3d-72d43cd0111e' User entered 'No (N)'	System	03 Sep 2020 02:27:12
	System	03 Sep 2020 02:27:12

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:02', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f29846d6-7e3b-4976-ac3d-72d43cd0111e' User entered 'No (N)'	System	03 Sep 2020 02:27:12
	System	03 Sep 2020 02:27:12

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:07', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f29846d6-7e3b-4976-ac3d-72d43cd0111e' User entered 'None (1)'	System	03 Sep 2020 02:27:12
	System	03 Sep 2020 02:27:12

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:10', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f29846d6-7e3b-4976-ac3d-72d43cd0111e' User entered '02 Sep 2020 19:27'	System	03 Sep 2020 02:27:12
	System	03 Sep 2020 02:27:12

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '02 Sep 2020 19:12'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:44:05



US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 2'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:07', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0c205b99-42da-4f00-bded-78516c696625'	System	04 Sep 2020 06:15:24
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 06:15:24

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:09', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0c205b99-42da-4f00-bded-78516c696625'	System	04 Sep 2020 06:15:24
User entered 'No (N)'	System	04 Sep 2020 06:15:24

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:11', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0c205b99-42da-4f00-bded-78516c696625'	System	04 Sep 2020 06:15:24
User entered 'No (N)'	System	04 Sep 2020 06:15:24

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:11:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:17', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0c205b99-42da-4f00-bded-78516c696625'	System	04 Sep 2020 06:15:24
User entered 'None (1)'	System	04 Sep 2020 06:15:24

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:19', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0c205b99-42da-4f00-bded-78516c696625' User entered '03 Sep 2020 23:15'	System	04 Sep 2020 06:15:24
	System	04 Sep 2020 06:15:24

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:44:05



US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 3'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:31', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0d89a8df-22ee-444f-9990-8aa1bd782eed'	System	04 Sep 2020 19:02:50
User entered 'None (1)'	System	04 Sep 2020 19:02:50

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:33', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0d89a8df-22ee-444f-9990-8aa1bd782eed'	System	04 Sep 2020 19:02:50
User entered 'No (N)'	System	04 Sep 2020 19:02:50

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:38', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0d89a8df-22ee-444f-9990-8aa1bd782eed'	System	04 Sep 2020 19:02:50
User entered 'No (N)'	System	04 Sep 2020 19:02:50

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:43', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0d89a8df-22ee-444f-9990-8aa1bd782eed'	System	04 Sep 2020 19:02:50
User entered 'None (1)'	System	04 Sep 2020 19:02:50

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:45', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '0d89a8df-22ee-444f-9990-8aa1bd782eed' User entered '04 Sep 2020 12:02'	System	04 Sep 2020 19:02:50
	System	04 Sep 2020 19:02:50

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:44:05



US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 4'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:40:16', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3dd06ef6-11fb-4442-ba37-d29be017a701'	System	05 Sep 2020 23:40:37
User entered 'None (1)'	System	05 Sep 2020 23:40:37

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:40:21', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3dd06ef6-11fb-4442-ba37-d29be017a701' User entered 'No (N)'	System	05 Sep 2020 23:40:37
	System	05 Sep 2020 23:40:37

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:40:24', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3dd06ef6-11fb-4442-ba37-d29be017a701' User entered 'No (N)'	System	05 Sep 2020 23:40:37
	System	05 Sep 2020 23:40:37

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:40:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3dd06ef6-11fb-4442-ba37-d29be017a701' User entered 'None (1)'	System	05 Sep 2020 23:40:37
	System	05 Sep 2020 23:40:37

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:40:35', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '3dd06ef6-11fb-4442-ba37-d29be017a701' User entered '05 Sep 2020 16:40'	System	05 Sep 2020 23:40:37
	System	05 Sep 2020 23:40:37

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:11:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:44:05



US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 5'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:11:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35



**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 6'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:17', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '74bedbb2-0bb3-4130-a7be-29234bb93d99'	System	07 Sep 2020 23:54:27
User entered 'None (1)'	System	07 Sep 2020 23:54:27

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:19', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '74bedbb2-0bb3-4130-a7be-29234bb93d99'	System	07 Sep 2020 23:54:27
User entered 'No (N)'	System	07 Sep 2020 23:54:27

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:21', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '74bedbb2-0bb3-4130-a7be-29234bb93d99'	System	07 Sep 2020 23:54:27
User entered 'No (N)'	System	07 Sep 2020 23:54:27

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:11:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:22', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '74bedbb2-0bb3-4130-a7be-29234bb93d99'	System	07 Sep 2020 23:54:27
User entered 'None (1)'	System	07 Sep 2020 23:54:27

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '74bedbb2-0bb3-4130-a7be-29234bb93d99'	System	07 Sep 2020 23:54:27
User entered '07 Sep 2020 16:54'	System	07 Sep 2020 23:54:27



**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 7'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:42', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '6aa68554-1aad-422f-b3ef-a4ae021db24e'	System	08 Sep 2020 22:37:55
User entered 'None (1)'	System	08 Sep 2020 22:37:55

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:45', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '6aa68554-1aad-422f-b3ef-a4ae021db24e' User entered 'No (N)'	System	08 Sep 2020 22:37:55
	System	08 Sep 2020 22:37:55

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:47', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '6aa68554-1aad-422f-b3ef-a4ae021db24e' User entered 'No (N)'	System	08 Sep 2020 22:37:55
	System	08 Sep 2020 22:37:55

US3112121

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:11:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:49', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '6aa68554-1aad-422f-b3ef-a4ae021db24e'	System	08 Sep 2020 22:37:55
User entered 'None (1)'	System	08 Sep 2020 22:37:55

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:51', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '6aa68554-1aad-422f-b3ef-a4ae021db24e' User entered '08 Sep 2020 15:37'	System	08 Sep 2020 22:37:55
	System	08 Sep 2020 22:37:55



**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:15', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '293c4770-a70e-43f8-9c34-f38f4dc3f006' User entered 'None (0)'	System	02 Sep 2020 23:03:33
	System	02 Sep 2020 23:03:33

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:17', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '293c4770-a70e-43f8-9c34-f38f4dc3f006' User entered 'None (0)'	System	02 Sep 2020 23:03:33
	System	02 Sep 2020 23:03:33

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:19', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '293c4770-a70e-43f8-9c34-f38f4dc3f006' User entered 'None (0)'	System	02 Sep 2020 23:03:33
	System	02 Sep 2020 23:03:33

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:21', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '293c4770-a70e-43f8-9c34-f38f4dc3f006' User entered 'None (0)'	System	02 Sep 2020 23:03:33
	System	02 Sep 2020 23:03:33

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:23', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '293c4770-a70e-43f8-9c34-f38f4dc3f006' User entered 'None (0)'	System	02 Sep 2020 23:03:33
	System	02 Sep 2020 23:03:33



US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '293c4770-a70e-43f8-9c34-f38f4dc3f006' User entered 'None (0)'	System	02 Sep 2020 23:03:33
	System	02 Sep 2020 23:03:33

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '293c4770-a70e-43f8-9c34-f38f4dc3f006' User entered 'No (N)'	System	02 Sep 2020 23:03:33
	System	02 Sep 2020 23:03:33

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T16:03:30', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '293c4770-a70e-43f8-9c34-f38f4dc3f006' User entered '02 Sep 2020 16:03'	System	02 Sep 2020 23:03:33
	System	02 Sep 2020 23:03:33

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '02 Sep 2020 15:47'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '02 Sep 2020 18:17'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:15', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a95237c9-5612-4c1e-9ff2-0fa5a4b00285'	System	03 Sep 2020 02:27:35
User entered 'None (0)'	System	03 Sep 2020 02:27:35

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:17', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a95237c9-5612-4c1e-9ff2-0fa5a4b00285'	System	03 Sep 2020 02:27:35
User entered 'None (0)'	System	03 Sep 2020 02:27:35



US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:19', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a95237c9-5612-4c1e-9ff2-0fa5a4b00285' User entered 'None (0)'	System	03 Sep 2020 02:27:35
	System	03 Sep 2020 02:27:35

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:22', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a95237c9-5612-4c1e-9ff2-0fa5a4b00285' User entered 'None (0)'	System	03 Sep 2020 02:27:35
	System	03 Sep 2020 02:27:35

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:24', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a95237c9-5612-4c1e-9ff2-0fa5a4b00285'	System	03 Sep 2020 02:27:35
User entered 'None (0)'	System	03 Sep 2020 02:27:35

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a95237c9-5612-4c1e-9ff2-0fa5a4b00285' User entered 'None (0)'	System	03 Sep 2020 02:27:35
	System	03 Sep 2020 02:27:35

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a95237c9-5612-4c1e-9ff2-0fa5a4b00285'	System	03 Sep 2020 02:27:35
User entered 'No (N)'	System	03 Sep 2020 02:27:35

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-02T19:27:31', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'a95237c9-5612-4c1e-9ff2-0fa5a4b00285'	System	03 Sep 2020 02:27:35
User entered '02 Sep 2020 19:27'	System	03 Sep 2020 02:27:35

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '02 Sep 2020 19:12'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:44:05



US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 2'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:23', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd2f6de9f-4977-4bba-9826-57ff4c74227c' User entered 'None (0)'	System	04 Sep 2020 06:15:42
	System	04 Sep 2020 06:15:42

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd2f6de9f-4977-4bba-9826-57ff4c74227c' User entered 'None (0)'	System	04 Sep 2020 06:15:42
	System	04 Sep 2020 06:15:42

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:26', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd2f6de9f-4977-4bba-9826-57ff4c74227c' User entered 'None (0)'	System	04 Sep 2020 06:15:42
	System	04 Sep 2020 06:15:42

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd2f6de9f-4977-4bba-9826-57ff4c74227c' User entered 'None (0)'	System	04 Sep 2020 06:15:42
	System	04 Sep 2020 06:15:42

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:29', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd2f6de9f-4977-4bba-9826-57ff4c74227c' User entered 'None (0)'	System	04 Sep 2020 06:15:42
	System	04 Sep 2020 06:15:42

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:31', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd2f6de9f-4977-4bba-9826-57ff4c74227c' User entered 'None (0)'	System	04 Sep 2020 06:15:42
	System	04 Sep 2020 06:15:42

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:37', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd2f6de9f-4977-4bba-9826-57ff4c74227c' User entered 'No (N)'	System	04 Sep 2020 06:15:42
	System	04 Sep 2020 06:15:42



**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-03T23:15:40', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd2f6de9f-4977-4bba-9826-57ff4c74227c' User entered '03 Sep 2020 23:15'	System	04 Sep 2020 06:15:42
	System	04 Sep 2020 06:15:42

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 3'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:51', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5a6b53f2-ff7a-47fd-98c7-b93b1d7b4ac2' User entered 'None (0)'	System	04 Sep 2020 19:03:14
	System	04 Sep 2020 19:03:14

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:53', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5a6b53f2-ff7a-47fd-98c7-b93b1d7b4ac2' User entered 'None (0)'	System	04 Sep 2020 19:03:14
	System	04 Sep 2020 19:03:14

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:55', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5a6b53f2-ff7a-47fd-98c7-b93b1d7b4ac2' User entered 'None (0)'	System	04 Sep 2020 19:03:14
	System	04 Sep 2020 19:03:14

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:57', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5a6b53f2-ff7a-47fd-98c7-b93b1d7b4ac2' User entered 'None (0)'	System	04 Sep 2020 19:03:14
	System	04 Sep 2020 19:03:14



**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:11:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:02:59', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5a6b53f2-ff7a-47fd-98c7-b93b1d7b4ac2' User entered 'None (0)'	System	04 Sep 2020 19:03:14
	System	04 Sep 2020 19:03:14

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:03:01', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5a6b53f2-ff7a-47fd-98c7-b93b1d7b4ac2'	System	04 Sep 2020 19:03:14
User entered 'None (0)'	System	04 Sep 2020 19:03:14

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:03:05', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5a6b53f2-ff7a-47fd-98c7-b93b1d7b4ac2'	System	04 Sep 2020 19:03:14
User entered 'No (N)'	System	04 Sep 2020 19:03:14

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-04T12:03:07', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5a6b53f2-ff7a-47fd-98c7-b93b1d7b4ac2'	System	04 Sep 2020 19:03:14
User entered '04 Sep 2020 12:03'	System	04 Sep 2020 19:03:14

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 4'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:40:49', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '65b5339d-0e67-4558-8ec2-34e40bdf98e3' User entered 'None (0)'	System	05 Sep 2020 23:41:20
	System	05 Sep 2020 23:41:20



US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:41:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '65b5339d-0e67-4558-8ec2-34e40bdf98e3' User entered 'None (0)'	System	05 Sep 2020 23:41:20
	System	05 Sep 2020 23:41:20

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:41:03', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '65b5339d-0e67-4558-8ec2-34e40bdf98e3' User entered 'None (0)'	System	05 Sep 2020 23:41:20
	System	05 Sep 2020 23:41:20

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:41:05', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '65b5339d-0e67-4558-8ec2-34e40bdf98e3' User entered 'None (0)'	System	05 Sep 2020 23:41:20
	System	05 Sep 2020 23:41:20

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:41:07', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '65b5339d-0e67-4558-8ec2-34e40bdf98e3' User entered 'None (0)'	System	05 Sep 2020 23:41:20
	System	05 Sep 2020 23:41:20

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:41:09', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '65b5339d-0e67-4558-8ec2-34e40bdf98e3' User entered 'None (0)'	System	05 Sep 2020 23:41:20
	System	05 Sep 2020 23:41:20

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:41:12', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '65b5339d-0e67-4558-8ec2-34e40bdf98e3' User entered 'No (N)'	System	05 Sep 2020 23:41:20
	System	05 Sep 2020 23:41:20

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-05T16:41:18', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '65b5339d-0e67-4558-8ec2-34e40bdf98e3' User entered '05 Sep 2020 16:41'	System	05 Sep 2020 23:41:20
	System	05 Sep 2020 23:41:20

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:44:05



**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 5'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35



US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:11:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 6'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:27', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e1971592-528e-433f-8d42-6ab45314389b' User entered 'None (0)'	System	07 Sep 2020 23:54:39
	System	07 Sep 2020 23:54:39

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:29', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e1971592-528e-433f-8d42-6ab45314389b' User entered 'None (0)'	System	07 Sep 2020 23:54:39
	System	07 Sep 2020 23:54:39

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:30', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e1971592-528e-433f-8d42-6ab45314389b' User entered 'None (0)'	System	07 Sep 2020 23:54:39
	System	07 Sep 2020 23:54:39



US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:31', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e1971592-528e-433f-8d42-6ab45314389b' User entered 'None (0)'	System	07 Sep 2020 23:54:39
	System	07 Sep 2020 23:54:39

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:32', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e1971592-528e-433f-8d42-6ab45314389b' User entered 'None (0)'	System	07 Sep 2020 23:54:39
	System	07 Sep 2020 23:54:39

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:33', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e1971592-528e-433f-8d42-6ab45314389b' User entered 'None (0)'	System	07 Sep 2020 23:54:39
	System	07 Sep 2020 23:54:39

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:35', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e1971592-528e-433f-8d42-6ab45314389b' User entered 'No (N)'	System	07 Sep 2020 23:54:39
	System	07 Sep 2020 23:54:39

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-07T16:54:38', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'e1971592-528e-433f-8d42-6ab45314389b' User entered '07 Sep 2020 16:54'	System	07 Sep 2020 23:54:39
	System	07 Sep 2020 23:54:39

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	02 Sep 2020 22:44:05
User entered 'Day 7'	System	02 Sep 2020 22:44:05



**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:55', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '32a21f8d-ea0b-46eb-a226-0d0618689bb3' User entered 'None (0)'	System	08 Sep 2020 22:38:23
	System	08 Sep 2020 22:38:23

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:56', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '32a21f8d-ea0b-46eb-a226-0d0618689bb3' User entered 'None (0)'	System	08 Sep 2020 22:38:23
	System	08 Sep 2020 22:38:23

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:37:58', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '32a21f8d-ea0b-46eb-a226-0d0618689bb3' User entered 'None (0)'	System	08 Sep 2020 22:38:23
	System	08 Sep 2020 22:38:23

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:38:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '32a21f8d-ea0b-46eb-a226-0d0618689bb3' User entered 'None (0)'	System	08 Sep 2020 22:38:23
	System	08 Sep 2020 22:38:23

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:38:01', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '32a21f8d-ea0b-46eb-a226-0d0618689bb3' User entered 'None (0)'	System	08 Sep 2020 22:38:23
	System	08 Sep 2020 22:38:23

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:38:03', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '32a21f8d-ea0b-46eb-a226-0d0618689bb3' User entered 'None (0)'	System	08 Sep 2020 22:38:23
	System	08 Sep 2020 22:38:23

US3112121

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:38:07', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '32a21f8d-ea0b-46eb-a226-0d0618689bb3' User entered 'No (N)'	System	08 Sep 2020 22:38:23
	System	08 Sep 2020 22:38:23

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-09-08T15:38:21', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '32a21f8d-ea0b-46eb-a226-0d0618689bb3' User entered '08 Sep 2020 15:38'	System	08 Sep 2020 22:38:23
	System	08 Sep 2020 22:38:23



**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:11:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:44:05

**US3112121**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'No (N)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:24:38

**US3112121**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered empty.	Karen Mylerberg (b) (4)	16 Sep 2020 23:24:38

**US3112121**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered empty.	Karen Mylerberg (b) (4)	16 Sep 2020 23:24:38

US3112121

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered empty.	Karen Mylerberg (b) (4)	16 Sep 2020 23:24:38

US3112121

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:24:43

**US3112121**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'I'	System	16 Sep 2020 23:24:43



**US3112121**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:24:54

**US3112121**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16 Sep 2020'	Karen Mylerberg (b) (4)	16 Sep 2020 23:24:54

**US3112121**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:24:54

US3112121

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	Karen Mylerberg (b) (4)	16 Sep 2020 23:24:54

US3112121

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:25:00

**US3112121**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'I'	System	16 Sep 2020 23:25:00

**US3112121**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Sep 2020 23:40:49

**US3112121**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '23 Sep 2020'	Karen Mylerberg (b) (4)	23 Sep 2020 23:40:49



**US3112121**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	23 Sep 2020 23:40:49

US3112121

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	Karen Mylerberg (b) (4)	23 Sep 2020 23:40:49

US3112121

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Sep 2020 23:40:57

**US3112121**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'I'	System	23 Sep 2020 23:40:57

**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:37:01

**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:37:01

**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:37:01

**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'VISIT3'	System	02 Oct 2020 21:37:01



**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38

**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '13:42'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38

**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '01 Oct 2020 13:42'	System	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '64'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38



**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'bpm'	System	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'breaths/min'	System	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '119'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38

**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	02 Oct 2020 21:39:38

**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '75'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'mmHg'	System	02 Oct 2020 21:39:38

US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54



US3112121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54

US3112121

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:40:22

US3112121

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:40:22

US3112121

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:58

US3112121

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:58

**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:11:31**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered '14:05'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:39:58

US3112121

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '01 Oct 2020 14:05'	System	02 Oct 2020 21:39:58

US3112121

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:49:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:40:06



**US3112121**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered '1'	System	02 Oct 2020 21:40:06

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 64'	System	06 Aug 2020 00:31:13

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:17', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered 'Yes (Y)'	System	07 Oct 2020 22:33:45

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

Have you been exposed to someone with 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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:24', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered 'Yes (Y)'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:32', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Oct 2020 22:33:45

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 22:26:17
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	Matthew Musikanth (b) (4)	10 Nov 2020 21:39:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:38', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered 'Yes (Y)'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45



**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '1'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '1'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742' User entered '0'	System	07 Oct 2020 22:33:45
	System	07 Oct 2020 22:33:45



**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742' User entered '0'	System	07 Oct 2020 22:33:45
	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered '0'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:32:56', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Oct 2020 22:33:45



US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:33:22', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered 'Yes (Y)'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:33:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742'	System	07 Oct 2020 22:33:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-07T15:33:34', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aa26da45-3dcb-436d-9627-56f198d0b742' User entered '07 Oct 2020 15:33:34'	System	07 Oct 2020 22:33:45
	System	07 Oct 2020 22:33:45

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '05 Oct 2020 00:01'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '09 Oct 2020 23:59'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 71'	System	06 Aug 2020 00:31:13

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-14T12:19:21', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f8b12725-c5cf-44ba-83d7-b7a876ae7267'	System	14 Oct 2020 19:19:36
User entered 'No (N)'	System	14 Oct 2020 19:19:36

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

Have you been exposed to someone with 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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-14T12:19:27', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f8b12725-c5cf-44ba-83d7-b7a876ae7267'	System	14 Oct 2020 19:19:36
User entered 'No (N)'	System	14 Oct 2020 19:19:36



**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-14T12:19:29', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f8b12725-c5cf-44ba-83d7-b7a876ae7267' User entered '14 Oct 2020 12:19:29'	System	14 Oct 2020 19:19:36
	System	14 Oct 2020 19:19:36

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '12 Oct 2020 00:01'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '16 Oct 2020 23:59'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 78'	System	06 Aug 2020 00:31:13

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-19T15:12:46', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '2a96aa2d-e1c3-4bc8-bf45-a8d831fa7ff7'	System	19 Oct 2020 22:12:56
User entered 'No (N)'	System	19 Oct 2020 22:12:56

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-19T15:12:49', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '2a96aa2d-e1c3-4bc8-bf45-a8d831fa7ff7'	System	19 Oct 2020 22:12:56
User entered 'No (N)'	System	19 Oct 2020 22:12:56

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-10-19T15:12:51', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '2a96aa2d-e1c3-4bc8-bf45-a8d831fa7ff7' User entered '19 Oct 2020 15:12:51'	System	19 Oct 2020 22:12:56
	System	19 Oct 2020 22:12:56

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '19 Oct 2020 00:01'	System	06 Aug 2020 00:31:13



**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '23 Oct 2020 23:59'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 92'	System	06 Aug 2020 00:31:13

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

[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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-02T07:27:11', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd08c0f82-d5e9-4273-b00d-f1a554b4c643'	System	02 Nov 2020 15:27:21
User entered 'No (N)'	System	02 Nov 2020 15:27:21

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

Have you been exposed to someone with 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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-02T07:27:16', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd08c0f82-d5e9-4273-b00d-f1a554b4c643'	System	02 Nov 2020 15:27:21
User entered 'No (N)'	System	02 Nov 2020 15:27:21

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-02T07:27:18', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd08c0f82-d5e9-4273-b00d-f1a554b4c643'	System	02 Nov 2020 15:27:21
User entered '02 Nov 2020 07:27:18'	System	02 Nov 2020 15:27:21

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '02 Nov 2020 00:01'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '06 Nov 2020 23:59'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 99'	System	06 Aug 2020 00:31:13



US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

[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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-11T12:08:40', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4e5193bd-0e48-4dee-8e18-10dd4a0b0c44' User entered 'No (N)'	System	11 Nov 2020 20:08:49
	System	11 Nov 2020 20:08:49

US3112121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:31

Have you been exposed to someone with 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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-11T12:08:43', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4e5193bd-0e48-4dee-8e18-10dd4a0b0c44' User entered 'No (N)'	System	11 Nov 2020 20:08:49
	System	11 Nov 2020 20:08:49

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-11T12:08:47', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4e5193bd-0e48-4dee-8e18-10dd4a0b0c44' User entered '11 Nov 2020 12:08:47'	System	11 Nov 2020 20:08:49
	System	11 Nov 2020 20:08:49

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '09 Nov 2020 00:01'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '13 Nov 2020 23:59'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered 'Day 106'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-16T00:16:15', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '79428f5a-697a-4bbf-97b4-565e33e3fcff'	System	16 Nov 2020 08:16:25
User entered 'No (N)'	System	16 Nov 2020 08:16:25

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Have you been exposed to someone with 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)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-16T00:16:20', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '79428f5a-697a-4bbf-97b4-565e33e3fcff' User entered 'No (N)'	System	16 Nov 2020 08:16:25
	System	16 Nov 2020 08:16:25



**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-16T00:16:23', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '79428f5a-697a-4bbf-97b4-565e33e3fcff' User entered '16 Nov 2020 00:16:23'	System	16 Nov 2020 08:16:25
	System	16 Nov 2020 08:16:25

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '16 Nov 2020 00:01'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:26:35
Data entry locked.	System	06 Aug 2020 00:31:13
User entered '20 Nov 2020 23:59'	System	06 Aug 2020 00:31:13

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-24T16:29:48', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'cf85a7da-7578-432b-ab4f-14d6b765685d' User entered 'No (N)'	System	25 Nov 2020 00:29:57
	System	25 Nov 2020 00:29:57

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-24T16:29:50', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'cf85a7da-7578-432b-ab4f-14d6b765685d' User entered 'No (N)'	System	25 Nov 2020 00:29:57

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-24T16:29:53', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'cf85a7da-7578-432b-ab4f-14d6b765685d' User entered '24 Nov 2020 16:29:53'	System	25 Nov 2020 00:29:57
	System	25 Nov 2020 00:29:57

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-29T12:00:14', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '10c69960-cfc1-4340-ace2-afe5a558af40' User entered 'No (N)'	System	29 Nov 2020 20:00:25
	System	29 Nov 2020 20:00:25

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Have you been exposed to someone with 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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-29T12:00:19', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '10c69960-cfc1-4340-ace2-afe5a558af40'	System	29 Nov 2020 20:00:25
User entered 'No (N)'	System	29 Nov 2020 20:00:25

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-11-29T12:00:22', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '10c69960-cfc1-4340-ace2-afe5a558af40' User entered '29 Nov 2020 12:00:22'	System	29 Nov 2020 20:00:25
	System	29 Nov 2020 20:00:25

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-07T17:59:19', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '44629c5a-ad3b-4833-bec4-9f358726ac61' User entered 'No (N)'	System	08 Dec 2020 01:59:31
	System	08 Dec 2020 01:59:31

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-07T17:59:25', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '44629c5a-ad3b-4833-bec4-9f358726ac61' User entered 'No (N)'	System	08 Dec 2020 01:59:31

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-07T17:59:28', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '44629c5a-ad3b-4833-bec4-9f358726ac61' User entered '07 Dec 2020 17:59:28'	System	08 Dec 2020 01:59:31
	System	08 Dec 2020 01:59:31

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-13T12:00:20', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '735b95e3-25a1-4bfe-9319-bc3910349c7d' User entered 'No (N)'	System	13 Dec 2020 20:00:28
	System	13 Dec 2020 20:00:28

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-13T12:00:23', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '735b95e3-25a1-4bfe-9319-bc3910349c7d' User entered 'No (N)'	System	13 Dec 2020 20:00:28



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-13T12:00:26', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '735b95e3-25a1-4bfe-9319-bc3910349c7d' User entered '13 Dec 2020 12:00:26'	System	13 Dec 2020 20:00:28
	System	13 Dec 2020 20:00:28

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-20T12:26:18', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5aaab104-4a11-404f-8af5-64b3c90c6503'	System	20 Dec 2020 20:26:24
User entered 'No (N)'	System	20 Dec 2020 20:26:24

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-20T12:26:20', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5aaab104-4a11-404f-8af5-64b3c90c6503'	System	20 Dec 2020 20:26:24
User entered 'No (N)'	System	20 Dec 2020 20:26:24

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-20T12:26:22', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '5aaab104-4a11-404f-8af5-64b3c90c6503' User entered '20 Dec 2020 12:26:22'	System	20 Dec 2020 20:26:24
	System	20 Dec 2020 20:26:24

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-25T00:01:13', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d43e63c-18a5-49a6-bb03-1dd6768609ac' User entered 'No (N)'	System	25 Dec 2020 08:01:24
	System	25 Dec 2020 08:01:24

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Have you been exposed to someone with 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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-25T00:01:17', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d43e63c-18a5-49a6-bb03-1dd6768609ac' User entered 'No (N)'	System	25 Dec 2020 08:01:24
	System	25 Dec 2020 08:01:24

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2020-12-25T00:01:21', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '9d43e63c-18a5-49a6-bb03-1dd6768609ac' User entered '25 Dec 2020 00:01:21'	System	25 Dec 2020 08:01:24
	System	25 Dec 2020 08:01:24

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2021-01-04T18:00:52', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'b6376174-7a15-4cb4-9972-958b28fe0448'	System	05 Jan 2021 02:01:01
User entered 'No (N)'	System	05 Jan 2021 02:01:01

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2021-01-04T18:00:55', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'b6376174-7a15-4cb4-9972-958b28fe0448'	System	05 Jan 2021 02:01:01
User entered 'No (N)'	System	05 Jan 2021 02:01:01

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DD933E1C-CBD3-4F88-9536-08FC8E9BA7E1)', Time: '2021-01-04T18:00:57', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'b6376174-7a15-4cb4-9972-958b28fe0448'	System	05 Jan 2021 02:01:01
User entered '04 Jan 2021 18:00:57'	System	05 Jan 2021 02:01:01

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-01-22T00:01:19', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '16b9317e-8c67-43e1-8025-2b874bca9a87'	System	22 Jan 2021 08:02:20
User entered 'No (N)'	System	22 Jan 2021 08:02:20

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-01-22T00:02:14', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '16b9317e-8c67-43e1-8025-2b874bca9a87'	System	22 Jan 2021 08:02:20
User entered 'No (N)'	System	22 Jan 2021 08:02:20

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-01-22T00:02:17', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '16b9317e-8c67-43e1-8025-2b874bca9a87'	System	22 Jan 2021 08:02:20
User entered '22 Jan 2021 00:02:17'	System	22 Jan 2021 08:02:20

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-01-29T10:33:30', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '061a7bf4-7d43-4c11-bcfc-5b76cf7c6999'	System	29 Jan 2021 18:33:40
User entered 'No (N)'	System	29 Jan 2021 18:33:40

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-01-29T10:33:34', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '061a7bf4-7d43-4c11-bcfc-5b76cf7c6999'	System	29 Jan 2021 18:33:40
User entered 'No (N)'	System	29 Jan 2021 18:33:40

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-01-29T10:33:37', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '061a7bf4-7d43-4c11-bcfc-5b76cf7c6999' User entered '29 Jan 2021 10:33:37'	System	29 Jan 2021 18:33:40
	System	29 Jan 2021 18:33:40

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-02-05T07:28:06', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd5f6a863-c12b-4be8-8661-cdb9e3adb2da' User entered 'No (N)'	System	05 Feb 2021 15:28:18
	System	05 Feb 2021 15:28:18

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-02-05T07:28:12', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd5f6a863-c12b-4be8-8661-cdb9e3adb2da'	System	05 Feb 2021 15:28:18
User entered 'No (N)'	System	05 Feb 2021 15:28:18

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-02-05T07:28:14', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'd5f6a863-c12b-4be8-8661-cdb9e3adb2da' User entered '05 Feb 2021 07:28:14'	System	05 Feb 2021 15:28:18
	System	05 Feb 2021 15:28:18

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-02-14T09:08:04', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '70f66cf0-3c12-4441-9cde-55944a9179ba' User entered 'No (N)'	System	14 Feb 2021 17:12:44
	System	14 Feb 2021 17:12:44

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-02-14T09:08:08', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '70f66cf0-3c12-4441-9cde-55944a9179ba' User entered 'No (N)'	System	14 Feb 2021 17:12:44



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-02-14T09:08:11', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '70f66cf0-3c12-4441-9cde-55944a9179ba' User entered '14 Feb 2021 09:08:11'	System	14 Feb 2021 17:12:44
	System	14 Feb 2021 17:12:44

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-02-21T20:39:58', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '26988f35-4e39-46d9-9b3f-465f14478421' User entered 'No (N)'	System	22 Feb 2021 04:40:08
	System	22 Feb 2021 04:40:08

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-02-21T20:40:01', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '26988f35-4e39-46d9-9b3f-465f14478421' User entered 'No (N)'	System	22 Feb 2021 04:40:08
	System	22 Feb 2021 04:40:08

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-02-21T20:40:04', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '26988f35-4e39-46d9-9b3f-465f14478421' User entered '21 Feb 2021 20:40:04'	System	22 Feb 2021 04:40:08
	System	22 Feb 2021 04:40:08

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-02T10:23:52-08:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'acdc9e36-550a-4b45-b0f8-8ed823556ee8' User entered 'No (N)'	System	02 Mar 2021 18:26:10
	System	02 Mar 2021 18:26:10

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-02T10:23:59-08:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'acdc9e36-550a-4b45-b0f8-8ed823556ee8'	System	02 Mar 2021 18:26:10
User entered 'No (N)'	System	02 Mar 2021 18:26:10

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-02T10:24:02-08:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'acdc9e36-550a-4b45-b0f8-8ed823556ee8'	System	02 Mar 2021 18:26:10
User entered '02 Mar 2021 10:24:02'	System	02 Mar 2021 18:26:10

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-05T08:18:55-08:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '547394e6-c33f-4b92-b3ee-611c0d5a7add'	System	05 Mar 2021 16:19:09
User entered 'No (N)'	System	05 Mar 2021 16:19:09

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-05T08:18:57-08:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '547394e6-c33f-4b92-b3ee-611c0d5a7add'	System	05 Mar 2021 16:19:09
User entered 'No (N)'	System	05 Mar 2021 16:19:09

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-05T08:19:02-08:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '547394e6-c33f-4b92-b3ee-611c0d5a7add' User entered '05 Mar 2021 08:19:02'	System	05 Mar 2021 16:19:09
	System	05 Mar 2021 16:19:09

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-14T12:31:47-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aea3ff11-f2d6-429c-ab63-8b084aa9e544'	System	14 Mar 2021 19:32:31
User entered 'No (N)'	System	14 Mar 2021 19:32:31

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-14T12:31:49-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aea3ff11-f2d6-429c-ab63-8b084aa9e544'	System	14 Mar 2021 19:32:31
User entered 'No (N)'	System	14 Mar 2021 19:32:31



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-14T12:31:53-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aea3ff11-f2d6-429c-ab63-8b084aa9e544'	System	14 Mar 2021 19:32:31
User entered '14 Mar 2021 12:31:53'	System	14 Mar 2021 19:32:31

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-21T12:00:13-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aca9731b-04bf-449d-98f0-ffda7b79c947'	System	21 Mar 2021 19:00:27
User entered 'No (N)'	System	21 Mar 2021 19:00:27

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-21T12:00:15-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aca9731b-04bf-449d-98f0-ffda7b79c947'	System	21 Mar 2021 19:00:27
User entered 'No (N)'	System	21 Mar 2021 19:00:27

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-21T12:00:20-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'aca9731b-04bf-449d-98f0-ffda7b79c947'	System	21 Mar 2021 19:00:27
User entered '21 Mar 2021 12:00:20'	System	21 Mar 2021 19:00:27

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-26T15:41:43-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'c6096f3b-debb-445e-b5a2-7a8854a80a21'	System	26 Mar 2021 22:41:51
User entered 'No (N)'	System	26 Mar 2021 22:41:51

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-26T15:41:45-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'c6096f3b-debb-445e-b5a2-7a8854a80a21'	System	26 Mar 2021 22:41:51
User entered 'No (N)'	System	26 Mar 2021 22:41:51

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-26T15:41:47-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'c6096f3b-debb-445e-b5a2-7a8854a80a21' User entered '26 Mar 2021 15:41:47'	System	26 Mar 2021 22:41:51
	System	26 Mar 2021 22:41:51

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-04-09T18:06:40-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4e1de7bb-d85d-4b64-a2ee-9e77ae290192'	System	10 Apr 2021 01:11:40
User entered 'No (N)'	System	10 Apr 2021 01:11:40

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-04-09T18:06:43-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4e1de7bb-d85d-4b64-a2ee-9e77ae290192'	System	10 Apr 2021 01:11:40
User entered 'No (N)'	System	10 Apr 2021 01:11:40

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-04-09T18:06:45-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4e1de7bb-d85d-4b64-a2ee-9e77ae290192'	System	10 Apr 2021 01:11:40
User entered '09 Apr 2021 18:06:45'	System	10 Apr 2021 01:11:40

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-04-16T08:35:50-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '01384c4b-034c-455d-be68-b5f1d7fd5b98'	System	16 Apr 2021 15:36:00
User entered 'No (N)'	System	16 Apr 2021 15:36:00

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-04-16T08:35:52-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '01384c4b-034c-455d-be68-b5f1d7fd5b98'	System	16 Apr 2021 15:36:00
User entered 'No (N)'	System	16 Apr 2021 15:36:00

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-04-16T08:35:55-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '01384c4b-034c-455d-be68-b5f1d7fd5b98'	System	16 Apr 2021 15:36:00
User entered '16 Apr 2021 08:35:55'	System	16 Apr 2021 15:36:00

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-04-24T08:05:53-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4043035c-f54f-4953-a050-e53eff3d4f44'	System	24 Apr 2021 15:05:59
User entered 'No (N)'	System	24 Apr 2021 15:05:59



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-04-24T08:05:55-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4043035c-f54f-4953-a050-e53eff3d4f44'	System	24 Apr 2021 15:05:59
User entered 'No (N)'	System	24 Apr 2021 15:05:59

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-04-24T08:05:58-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '4043035c-f54f-4953-a050-e53eff3d4f44'	System	24 Apr 2021 15:05:59
User entered '24 Apr 2021 08:05:58'	System	24 Apr 2021 15:05:59

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-05-02T12:00:19-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f58a527c-929b-43ed-8a60-09162a8a2af5'	System	02 May 2021 19:00:57
User entered 'No (N)'	System	02 May 2021 19:00:57

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

Have you been exposed to someone with 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 (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-05-02T12:00:20-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f58a527c-929b-43ed-8a60-09162a8a2af5'	System	02 May 2021 19:00:57
User entered 'No (N)'	System	02 May 2021 19:00:57

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-05-02T12:00:23-07:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: 'f58a527c-929b-43ed-8a60-09162a8a2af5'	System	02 May 2021 19:00:57
User entered '02 May 2021 12:00:23'	System	02 May 2021 19:00:57



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:02:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 14:02:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 14:02:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:02:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 14:02:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 14:02:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:02:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 14:02:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 14:02:07



**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 14:02:07

**US3112121**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:11:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:02:07
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 14:02:07

US3112121

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:11:31**

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)	29 Apr 2021 19:47:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-02T10:24:19-08:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '2a2852bc-79d8-477a-9109-26d155b4dd26'	System	02 Mar 2021 18:26:00
User entered 'No (N)'	System	02 Mar 2021 18:26:00

**US3112121**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:47:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82DBA35C-A313-4336-8BDA-75FB35869EC6)', Time: '2021-03-02T10:24:26-08:00', User OID: 'PatientReportedOutcome (US3112121)', ODM File OID: '2a2852bc-79d8-477a-9109-26d155b4dd26'	System	02 Mar 2021 18:26:00
User entered '02 Mar 2021 10:24:26'	System	02 Mar 2021 18:26:00

**US3112121**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:12
User entered 'Yes (Y)'	Natalie Moy (b) (4)	01 Dec 2020 16:15:11

US3112121

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:12
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Dec 2020 16:15:36
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	01 Dec 2020 16:15:36
User entered '27 Oct 2020' reason for change: Data Entry Error	Natalie Moy (b) (4)	01 Dec 2020 16:15:36
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Dec 2020 16:15:11
User entered '30 Nov 2020'	Natalie Moy (b) (4)	01 Dec 2020 16:15:11

**US3112121**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:12
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4)	01 Dec 2020 16:15:11



US3112121

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:12
User entered empty.	Natalie Moy (b) (4)	01 Dec 2020 16:15:11

**US3112121**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:45:12
User entered 'Yes (Y)'	Natalie Moy (b) (4)	01 Dec 2020 16:15:39

**US3112121**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:01:54
User entered 'I'	System	01 Dec 2020 16:15:39

US3112121

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	01 Dec 2020 16:15:58

**US3112121**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '30 Nov 2020'	Natalie Moy (b) (4)	01 Dec 2020 16:15:58

**US3112121**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4)	01 Dec 2020 16:15:58

US3112121

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Natalie Moy (b) (4)	01 Dec 2020 16:15:58

US3112121

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	01 Dec 2020 16:16:03



**US3112121**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User entered 'I'	System	01 Dec 2020 16:16:03

**US3112121**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Dec 2020 17:59:13

US3112121

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '30 Dec 2020'	Karen Mylerberg (b) (4)	30 Dec 2020 17:59:13

**US3112121**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	30 Dec 2020 17:59:13

US3112121

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Karen Mylerberg (b) (4)	30 Dec 2020 17:59:13

US3112121

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Dec 2020 17:59:20

**US3112121**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User entered 'I'	System	30 Dec 2020 17:59:20

**US3112121**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Jan 2021 21:07:19



**US3112121**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '29 Jan 2021'	Brenda Grande (b) (4)	29 Jan 2021 21:07:19

**US3112121**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	29 Jan 2021 21:07:19

US3112121

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Brenda Grande (b) (4)	29 Jan 2021 21:07:19

US3112121

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Jan 2021 21:07:11

**US3112121**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:06
User entered 'I'	System	29 Jan 2021 21:07:11

US3112121

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Mar 2021 17:05:58

US3112121

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '3 Mar 2021'	Natalie Moy (b) (4)	08 Mar 2021 17:05:58

US3112121

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	08 Mar 2021 17:05:58



**US3112121**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User entered 'VISIT4'	System	08 Mar 2021 17:05:58

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 18:20:42

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '03 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:20:42

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '16:25'	(b) (4), (b) (6)	30 Mar 2021 18:20:42

**US3112121**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User entered '03 Mar 2021 16:25'	System	30 Mar 2021 18:20:42

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '98.2' F	(b) (4), (b) (6)	30 Mar 2021 18:20:42

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 18:20:42

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:20:42



US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '60'	(b) (4), (b) (6)	30 Mar 2021 18:20:42

**US3112121**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User entered 'bpm'	System	30 Mar 2021 18:20:42

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '14'	(b) (4), (b) (6)	30 Mar 2021 18:20:42

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User entered 'breaths/min'	System	30 Mar 2021 18:20:42

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '128'	(b) (4), (b) (6)	30 Mar 2021 18:20:42

**US3112121**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User entered 'mmHg'	System	30 Mar 2021 18:20:42

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '88'	(b) (4), (b) (6)	30 Mar 2021 18:20:42

**US3112121**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User entered 'mmHg'	System	30 Mar 2021 18:20:42



US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08

US3112121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08

US3112121

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'No (N)'	Natalie Moy (b) (4)	08 Mar 2021 17:06:08

US3112121

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Natalie Moy (b) (4)	08 Mar 2021 17:06:08

US3112121

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Mar 2021 17:06:25

US3112121

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '3 Mar 2021'	Natalie Moy (b) (4)	08 Mar 2021 17:06:25

**US3112121**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:11:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '16:25'	Natalie Moy (b) (4)	08 Mar 2021 17:06:25

**US3112121**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:11:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User entered '3 Mar 2021 16:25'	System	08 Mar 2021 17:06:25



US3112121

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Mar 2021 17:06:30

**US3112121**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:07:08
User entered 'I'	System	08 Mar 2021 17:06:30

**US3112121**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:07
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Brenda Grande (b) (4)	31 Mar 2021 22:46:35

**US3112121**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:07
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '31 Mar 2021'	Brenda Grande (b) (4)	31 Mar 2021 22:46:35

**US3112121**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:11:31**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:07
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	31 Mar 2021 22:46:35

US3112121

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:07
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Brenda Grande (b) (4)	31 Mar 2021 22:46:35

US3112121

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:07
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Brenda Grande (b) (4)	31 Mar 2021 22:46:26

**US3112121**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:07
User entered 'I'	System	31 Mar 2021 22:46:26



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:11:31

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '05 Oct 2020'	Matthew Musikanth (b) (4)	06 Oct 2020 17:37:28

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:11:31**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '17:02'	Matthew Musikanth (b) (4)	06 Oct 2020 17:37:28

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:11:31**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User entered '05 Oct 2020 17:02'	System	06 Oct 2020 17:37:28

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:11:31

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:37:28

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:11:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:37:28

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	10 Nov 2020 21:39:09
User entered 'Day 1 (Day 1)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User closed query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (05 Oct 2020). Please review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 15:50:35
Query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (05 Oct 2020). Please review and update accordingly, else clarify.' answered with 'sx start date was 03OCT2020 and has been added ' (Site from DM).	Brenda Grande (b) (4)	07 Jan 2021 19:52:29
User opened query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (05 Oct 2020). Please review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:00:39
User entered '05 Oct 2020'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '0'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '96'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User entered '%'	System	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '98.5' F	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:11:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:38:50

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	10 Nov 2020 21:39:09
User entered 'Day 2 (Day 2)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '06 Oct 2020'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '0'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '97'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User entered '%'	System	12 Oct 2020 22:06:24



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:11:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:24

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	10 Nov 2020 21:39:09
User entered 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '07 Oct 2020'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '0'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '97'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User entered '%'	System	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:11:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:06:57

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	10 Nov 2020 21:39:09
User entered 'Day 4 (Day 4)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29



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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '08 Oct 2020'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '0'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '97'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User entered '%'	System	12 Oct 2020 22:07:29

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '97.7' F	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29



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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29



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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:11:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:07:29

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	10 Nov 2020 21:39:09
User entered 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '09 Oct 2020'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 15:11:31**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '0'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03



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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '97'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 15:11:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User entered '%'	System	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '97.8' F	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03



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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

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Folder: Covid-19 Assessment 05 Oct 2020

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03



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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:11:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	12 Oct 2020 22:08:03

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Day 1 (Day 1)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

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**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 15:11:31**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '03 Oct 2020'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User closed query 'Per CDM: It appears Assessment Not Done is checked but data is present on log lines 6 and 7. Please review update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 16:17:51
Query 'Per CDM: It appears Assessment Not Done is checked but data is present on log lines 6 and 7. Please review update accordingly.' answered with 'patient reported sx for those days no other data available ' (Site from DM).	Brenda Grande (b) (4)	07 Jan 2021 19:51:37
User opened query 'Per CDM: It appears Assessment Not Done is checked but data is present on log lines 6 and 7. Please review update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:03:06
User entered '1' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	10 Nov 2020 21:39:17
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 15:11:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User entered '%'	System	10 Nov 2020 21:38:13



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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13



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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 15:11:31**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:11:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13



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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:13

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Day 2 (Day 2)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '04 Oct 2020'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '1' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	10 Nov 2020 21:39:17
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 15:11:31**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User entered '%'	System	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43



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Folder: Covid-19 Assessment 05 Oct 2020

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43



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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

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Folder: Covid-19 Assessment 05 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:11:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:38:43

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:31

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '05 Oct 2020'	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:08



**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 15:11:31**

[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 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:08

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:31

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 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User closed query 'Per CDM RQ: Response noted. Please update and respond to the query once the data is available' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:26:50
Query 'Per CDM RQ: Response noted. Please update and respond to the query once the data is available' answered with 'updated' (Site from DM).	Natalie Moy (b) (4)	19 Oct 2020 20:15:48
User entered 'No (N)' reason for change: New Information	Natalie Moy (b) (4)	19 Oct 2020 20:15:42
User opened query 'Per CDM RQ: Response noted. Please update and respond to the query once the data is available' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 16:32:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 16:32:48
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:13
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 17:39:08
User entered empty.	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:08

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 15:11:31**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '05 Oct 2020'	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:08

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 15:11:31**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:08

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:31

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:08

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:31

[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 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:08

**US3112121**

**Folder: Covid-19 Assessment 05 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 15:11:31**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:08

US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Matthew Musikanth (b) (4)	06 Oct 2020 17:39:08



US3112121

Folder: Covid-19 Assessment 05 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:11:31

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:49
User entered '0'	System	19 Oct 2020 20:15:42

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User accepted default value 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '07 Oct 2020'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User accepted default value 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

US3112121

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:11:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Natalie Moy (b) (4)	07 Dec 2020 18:42:34
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

US3112121

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:11:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:54:46
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'mistake, as the saliva sample from day 3 turned out negative' (Site from DM).	Natalie Moy (b) (4)	07 Dec 2020 18:45:17
User entered empty; reason for change Data Entry Error	Natalie Moy (b) (4)	07 Dec 2020 18:42:34
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:28:52
User entered '09 Oct 2020'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User accepted default value 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09



**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:11:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User accepted default value 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:11:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:11:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:11:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User accepted default value 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:11:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:11:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09



**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:11:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User accepted default value 'Day 21 (Day 21)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:11:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:11:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:11:31**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User accepted default value 'Day 28 (Day 28)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:11:31**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

**US3112121**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:11:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Matthew Musikanth (b) (4)	16 Oct 2020 17:48:09

US3112121

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:41:03

**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '05 Oct 2020'	Matthew Musikanth (b) (4)	06 Oct 2020 17:41:03



**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:41:03

**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User entered 'SICKD1'	System	06 Oct 2020 17:41:03

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '05 Oct 2020'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16

**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '17:02'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16

**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User entered '05 Oct 2020 17:02'	System	06 Oct 2020 17:42:16

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered missing code ND - Not Done.	Matthew Musikanth	06 Oct 2020 17:42:16
DataPoint set to visible.	(b) (4) System	06 Oct 2020 17:41:03

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered missing code ND - Not Done.	Matthew Musikanth	06 Oct 2020 17:42:16
DataPoint set to visible.	(b) (4) System	06 Oct 2020 17:41:03



US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '98.2' F	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered empty.	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16

**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '62'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16

**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User entered 'bpm'	System	06 Oct 2020 17:42:16

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '14'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User entered 'breaths/min'	System	06 Oct 2020 17:42:16

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '128'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16



**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User entered 'mmHg'	System	06 Oct 2020 17:42:16

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '70'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:16

**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:11:31**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User entered 'mmHg'	System	06 Oct 2020 17:42:16

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49

US3112121

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49

US3112121

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:34

US3112121

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '05 Oct 2020'	Matthew Musikanth (b) (4)	06 Oct 2020 17:42:34

US3112121

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:11:31

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Oct 2020 17:43:00



**US3112121**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 15:11:31**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '05 Oct 2020'	Matthew Musikanth (b) (4)	06 Oct 2020 17:43:00

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:30

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '21 Jan 2021'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:30

US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:31

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:30

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:11:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 23:37:30

US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:11:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '21 Jan 2021'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:57

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:11:31**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:48
User entered '0'	Brenda Grande (b) (4)	08 Apr 2021 16:55:53
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:38:02

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:11:31**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:57



US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:11:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:59:42
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:48
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	08 Apr 2021 17:06:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brenda Grande (b) (4)	08 Apr 2021 16:55:53
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:27:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:38:02

US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:11:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '21 Jan 2021'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:57

US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:11:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'mRNA-1273 (mRNA-1273)'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:57

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:11:31**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'mRNA-1273 (mRNA-1273)'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:57

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:11:31**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'mRNA-1273 (mRNA-1273)'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:57

US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:11:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'No (N)'	Karen Mylerberg (b) (4)	22 Jan 2021 23:37:57

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:11:31**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User entered empty.	System	22 Jan 2021 23:37:57

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:11:31**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User entered empty.	System	22 Jan 2021 23:37:57



US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Jan 2021 23:38:10

US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '21 Jan 2021'	Karen Mylerberg (b) (4)	22 Jan 2021 23:38:10

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:11:31**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '10:20'	Karen Mylerberg (b) (4)	22 Jan 2021 23:38:10

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:11:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User entered '21 Jan 2021 10:20'	System	22 Jan 2021 23:38:10

US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:11:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	22 Jan 2021 23:38:22

US3112121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:11:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '21 Jan 2021'	Karen Mylerberg (b) (4)	22 Jan 2021 23:38:22

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:11:31**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '10:14'	Karen Mylerberg (b) (4)	22 Jan 2021 23:38:22

**US3112121**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:11:31**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:34
User entered '21 Jan 2021 10:14'	System	22 Jan 2021 23:38:22



US3112121

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:11:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:52
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 22:46:31
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 22:27:26

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:00
User entered	System	02 Oct 2020 12:39:54
'USA-US062-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	02 Oct 2020 12:39:54
User entered 'New'		

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
User closed query 'PV Query: Was the SAE considered a worsening of the subject's medical history of melanoma?' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:26:42
Query 'PV Query: Was the SAE considered a worsening of the subject's medical history of melanoma?' answered with 'new melanoma spot ' (Site from Safety).	Natalie Moy (b) (4)	19 Oct 2020 20:17:47
User opened query 'PV Query: Was the SAE considered a worsening of the subject's medical history of melanoma?' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:31:50
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 22:33:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 22:33:01
Data point term sent to Coder	System	01 Oct 2020 22:32:15
User entered 'Melanoma'	Matthew Musikanth (b) (4)	01 Oct 2020 22:31:53

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'Yes (Y)'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'No (N)'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'No (N)'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
	(b) (4), (b) (6)	
User closed query 'PV Query: The event started on 09 Sep 2020 however biopsy was noted on 04 Sep 2020. Please clarify or update event start date.' (Site from Safety).		20 Oct 2020 16:26:20
Query 'PV Query: The event started on 09 Sep 2020 however biopsy was noted on 04 Sep 2020. Please clarify or update event start date.' answered with 'melanoma was noticed on 9sept2020 but excised on the 21sept2020' (Site from Safety).	Natalie Moy (b) (4)	19 Oct 2020 20:18:11
User opened query 'PV Query: The event started on 09 Sep 2020 however biopsy was noted on 04 Sep 2020. Please clarify or update event start date.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:40:11
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered '09 Sep 2020'	Matthew Musikanth (b) (4)	01 Oct 2020 22:31:53

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered empty.	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	



**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 22:31:53

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:19:23
DataPoint Un-verified.	Matthew Musikanth	27 Oct 2020 21:04:55
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth	27 Oct 2020 21:04:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'Yes (Y)'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:19:26
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 17:15:01
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	27 Oct 2020 21:05:14
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	27 Oct 2020 21:05:14
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED' (Site from Safety).	Matthew Musikanth (b) (4)	27 Oct 2020 21:05:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	27 Oct 2020 21:04:55
DataPoint Un-verified.	Matthew Musikanth (b) (4)	27 Oct 2020 21:04:55
User entered '21 Sep 2020' reason for change: New Information	Matthew Musikanth (b) (4)	27 Oct 2020 21:04:55
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:32:07
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered empty.	Matthew Musikanth (b) (4)	01 Oct 2020 22:31:53

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered empty.	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 22:31:53

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'Grade 4 (Grade 4)'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'Yes (Y)'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered '0'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	



US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:20:05
User closed query 'PV Query: Life-threatening serious criteria should be used if subject was at immediate risk of death (i.e. cardiac arrest requiring resuscitation). If the subject was not at immediate risk for death, please consider removing this as a serious criteria.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:27:34
Query 'PV Query: Life-threatening serious criteria should be used if subject was at immediate risk of death (i.e. cardiac arrest requiring resuscitation). If the subject was not at immediate risk for death, please consider removing this as a serious criteria.' answered with 'updated' (Site from Safety).	Natalie Moy (b) (4)	19 Oct 2020 20:18:49
DataPoint Un-verified.	(b) (4)	19 Oct 2020 20:18:43
User entered '0' reason for change: Data Entry Error	Natalie Moy (b) (4)	19 Oct 2020 20:18:43
User opened query 'PV Query: Life-threatening serious criteria should be used if subject was at immediate risk of death (i.e. cardiac arrest requiring resuscitation). If the subject was not at immediate risk for death, please consider removing this as a serious criteria.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:41:33
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered '1'	Matthew Musikanth (b) (4)	01 Oct 2020 22:31:53

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered '0'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered empty.	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered empty.	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered empty.	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered empty.	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

US3112121

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered '0'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered '0'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'I'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:19:52
User closed query 'PV Query: As the last dose of study drug was given on 02Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:27:01
Query 'PV Query: As the last dose of study drug was given on 02Sep2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Natalie Moy (b) (4)	19 Oct 2020 20:18:57
DataPoint Un-verified.	(b) (4)	
	Natalie Moy (b) (4)	19 Oct 2020 20:18:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	
	Natalie Moy (b) (4)	19 Oct 2020 20:18:43
User opened query 'PV Query: As the last dose of study drug was given on 02Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:32:34
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'None (NONE)'	Matthew Musikanth (b) (4)	01 Oct 2020 22:31:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

None

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered '0'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered '0'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'I'	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:20:32
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 17:15:06
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	Matthew Musikanth (b) (4)	27 Oct 2020 21:05:27
DataPoint Un-verified.	Matthew Musikanth (b) (4)	27 Oct 2020 21:05:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Matthew Musikanth (b) (4)	27 Oct 2020 21:05:14
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:32:22
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'Unknown (UNKNOWN)'	Matthew Musikanth (b) (4)	01 Oct 2020 22:31:53



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered empty.	Matthew Musikanth	01 Oct 2020 22:31:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
	(b) (4), (b) (6)	28 Oct 2020 17:15:12
User closed query 'PV Query: Please provide pathology report.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 17:15:09
User closed query 'PV Query: Please provide any additional 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).' (Site from Safety).		
Query 'PV Query: Please provide pathology report.' answered with 'Final diagnosis, scar residual with melanoma in situ, completely excised. Margins are free of melanoma. ' (Site from Safety).	Matthew Musikanth (b) (4)	27 Oct 2020 21:12:46
Query 'PV Query: Please provide any additional 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).' answered with 'None' (Site from Safety).	Matthew Musikanth (b) (4)	27 Oct 2020 21:05:44
Query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:10:55
User closed query 'PV Query: Please add subject's previous history of melanoma to medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:27:15
Query 'PV Query: Please add subject's previous history of melanoma to medical history eCRF.' answered with 'updated' (Site from Safety).	Natalie Moy (b) (4)	19 Oct 2020 20:19:37
User opened query 'PV Query: Please provide pathology report.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:40:56
User opened query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:40:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:40:34
User opened query 'PV Query: Please add subject's previous history of melanoma to medical history eCRF.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 18:31:37
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:06:51
User entered 'Pt. reports seen by dermatologist for routine check up and noted to have suspicious mole on back. Excised. biopsy positive for melanoma, awaiting full pathology report. Patient reports, history of melanoma x2, not reported at screening, 2011 and 2019.	Matthew Musikanth (b) (4)	01 Oct 2020 22:31:53
Biopsy 04sep2020 diagnosis melanoma 09sep2020 excised 21sep2020 awaiting pathology.'		

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 22:31:53

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 22:31:53

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Postoperative wound infection, LLT: Surgical site infection - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 21:15:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 21:15:32
Data point term sent to Coder	System	27 Oct 2020 21:14:19
User entered 'Surgical Site Infection'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

US3112121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered '21 Oct 2020'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User entered empty.	System	27 Oct 2020 21:14:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:00:01
DataPoint Un-verified.	Matthew Musikanth	29 Oct 2020 20:51:02
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth	29 Oct 2020 20:51:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'Yes (Y)'	Matthew Musikanth	27 Oct 2020 21:14:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:00:03
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	29 Oct 2020 20:51:02
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	29 Oct 2020 20:51:02
DataPoint Un-verified.	Matthew Musikanth (b) (4)	29 Oct 2020 20:51:02
User entered '28 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 20:51:02
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	29 Oct 2020 20:50:50
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User entered empty.	System	27 Oct 2020 21:14:02

US3112121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

US3112121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

US3112121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

US3112121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

US3112121

Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02



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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'I'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

US3112121

Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:59:55
User closed query 'Please clarify. Source indicates resolved with end date of 28Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:59:52
Query 'Please clarify. Source indicates resolved with end date of 28Oct2020. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	29 Oct 2020 20:51:07
DataPoint Un-verified.	Matthew Musikanth (b) (4)	29 Oct 2020 20:50:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 20:50:50
User opened query 'Please clarify. Source indicates resolved with end date of 28Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:30:45
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:29:57
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:02

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User entered '0'	System	27 Oct 2020 21:14:02

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17
User entered '1'	System	27 Oct 2020 21:14:02



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:17

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 15:25:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 15:25:01
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 17:44:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 17:44:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:53:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:53:49
Data point term sent to Coder	System	10 Nov 2020 21:37:10
User entered 'Viral Illness'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'No (N)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'No (N)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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Folder: Adverse Events

Form: Adverse Events (3)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '03 Oct 2020'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered empty.	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09



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**Folder: Adverse Events**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User entered empty.	System	10 Nov 2020 21:37:09

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'No (N)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '06 Oct 2020'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:11:31**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered empty.	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:11:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User entered empty.	System	10 Nov 2020 21:37:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'No (N)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

US3112121

Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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Folder: Adverse Events

Form: Adverse Events (3)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered empty.	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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Folder: Adverse Events

Form: Adverse Events (3)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered empty.	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered empty.	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered empty.	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

US3112121

Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

US3112121

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09



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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'I'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered '0'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09



US3112121

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered empty.	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:22
User entered empty.	Matthew Musikanth (b) (4)	10 Nov 2020 21:37:09

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User entered '0'	System	10 Nov 2020 21:37:09

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19
User entered '1'	System	10 Nov 2020 21:37:09

**US3112121**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:36:19

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:11:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:21:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	06 Oct 2020 23:19:22
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:43:53

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 23:22:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 23:22:18
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 23:21:26
User entered 'FLu Vaccine'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered 'Yes (Y)'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	



US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered 'Flu Vaccine'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered '.5'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered 'mL (mL)'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered empty.	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered 'once (ONCE)'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered empty.	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

US3112121

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered 'Intramuscular (INTRAMUSCULAR)'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:31**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered empty.	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	



**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered '30 Sep 2020'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered '0'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered 'No (N)'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:31**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered '30 Sep 2020'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:33:32
User entered 'No (N)'	Matthew Musikanth	06 Oct 2020 23:20:26
	(b) (4)	

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 23:20:26

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 23:20:26

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 23:20:26



US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:13:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:13:35
Data point term sent to Coder	System	27 Oct 2020 21:15:20
User entered 'Doxycycline'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered 'Surgical Site Infection'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered '100'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49



**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered empty.	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered '21 Oct 2020'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered '0'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:06:42
User closed query 'Please clarify. Source indicates stop date of 28Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 21:06:40
Query 'Please clarify. Source indicates stop date of 28Oct2020. Please confirm and update as necessary.' answered with 'Updated' (Site from CRA).	Matthew Musikanth (b) (4)	29 Oct 2020 21:06:10
DataPoint Un-verified.	Matthew Musikanth (b) (4)	29 Oct 2020 21:06:05
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	29 Oct 2020 21:06:05
User opened query 'Please clarify. Source indicates stop date of 28Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:25:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:06:44
DataPoint Un-verified.	Matthew Musikanth	29 Oct 2020 21:06:05
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4)	29 Oct 2020 21:06:05
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered empty.	Matthew Musikanth	27 Oct 2020 21:14:49
	(b) (4)	

US3112121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:24:46
User entered 'No (N)'	Matthew Musikanth (b) (4)	27 Oct 2020 21:14:49

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User entered '2'	System	27 Oct 2020 21:14:49



**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User entered '1'	System	27 Oct 2020 21:14:49

**US3112121**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:52:03
User entered '804 (804)'	System	27 Oct 2020 21:14:49

US3112121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:11:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:07:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Oct 2020 22:47:28

US3112121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:31

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User closed query 'Per DM: Procedure/Surgery date doesn't match with the Adverse event recorded. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:12:14
Query 'Per DM: Procedure/Surgery date doesn't match with the Adverse event recorded. Please reconcile. ' answered with 'melanoma notices 9sept2020 but excised on the 21' (Site from DM).	Natalie Moy (b) (4)	19 Oct 2020 20:16:32
User opened query 'Per DM: Procedure/Surgery date doesn't match with the Adverse event recorded. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 17:04:18
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:07:23
User entered '21 Sep 2020'	Matthew Musikanth (b) (4)	01 Oct 2020 22:47:58

US3112121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:07:23
User entered 'Melanoma excised'	Matthew Musikanth	01 Oct 2020 22:47:58
	(b) (4)	

US3112121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:07:23
User entered 'Adverse Event (AE)'	Matthew Musikanth	01 Oct 2020 22:47:58
	(b) (4)	

US3112121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:31

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:07:23
User entered empty.	Matthew Musikanth	01 Oct 2020 22:47:58
	(b) (4)	

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'USA-US062-2020-MRNA-1273-P301000005'	System	02 Oct 2020 12:39:54



**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:22:21
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:28:25
Un-reviewed for Safety.	System	19 Oct 2020 20:18:43
DataPoint Un-verified.	System	19 Oct 2020 20:18:43
User entered 'No (N)'	System	19 Oct 2020 20:18:43
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Laurie'	System	02 Oct 2020 12:39:54



US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Han-Conrad'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered '9040 Friars Rd St 540'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'San Diego'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'CA'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered '92108'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:28:25
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
User entered 'US'	System	02 Oct 2020 12:40:33

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 17:15:42
User entered '2'	System	20 Oct 2020 16:28:40
User entered '1'	System	02 Oct 2020 12:40:33

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'USA-US062-2020-MRNA-1273-P301000005'	System	02 Oct 2020 12:39:54



**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:22:21
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:28:25
Un-reviewed for Safety.	System	19 Oct 2020 20:18:43
DataPoint Un-verified.	System	19 Oct 2020 20:18:43
User entered 'No (N)'	System	19 Oct 2020 20:18:43
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Laurie'	System	02 Oct 2020 12:39:54



US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Han-Conrad'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered '9040 Friars Rd St 540'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'San Diego'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'CA'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered '92108'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:28:25
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
User entered 'US'	System	02 Oct 2020 12:40:33

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 17:15:42
User entered '2'	System	20 Oct 2020 16:28:40
User entered '1'	System	02 Oct 2020 12:40:33

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:11:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
User entered '02/Oct/2020 08:40'	System	02 Oct 2020 12:40:33



US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:11:31

**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.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:28:25
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
User entered '1' reason for change: New Information	(b) (4), (b) (6)	02 Oct 2020 12:40:33
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:40:16

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'USA-US062-2020-MRNA-1273-P301000005'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:22:21
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:28:25
Un-reviewed for Safety.	System	19 Oct 2020 20:18:43
DataPoint Un-verified.	System	19 Oct 2020 20:18:43
User entered 'No (N)'	System	19 Oct 2020 20:18:43
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54



US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Laurie'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Han-Conrad'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered '9040 Friars Rd St 540'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'San Diego'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'CA'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered '92108'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:28:25
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
User entered 'US'	System	02 Oct 2020 12:40:33



**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 17:15:42
User entered '2'	System	20 Oct 2020 16:28:40
User entered '1'	System	02 Oct 2020 12:40:33

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:11:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '20/Oct/2020 12:28'	System	20 Oct 2020 16:28:40

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:11:31

**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.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:15:27
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 16:28:40

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'USA-US062-2020-MRNA-1273-P301000005'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:22:21
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:28:25
Un-reviewed for Safety.	System	19 Oct 2020 20:18:43
DataPoint Un-verified.	System	19 Oct 2020 20:18:43
User entered 'No (N)'	System	19 Oct 2020 20:18:43
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54



US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'No (N)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Yes (Y)'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Laurie'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'Han-Conrad'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered '9040 Friars Rd St 540'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'San Diego'	System	02 Oct 2020 12:39:54

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered 'CA'	System	02 Oct 2020 12:39:54



**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:40:12
User entered '92108'	System	02 Oct 2020 12:39:54

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:28:25
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 23:35:05
User entered 'US'	System	02 Oct 2020 12:40:33

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:11:31**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 17:15:42
User entered '2'	System	20 Oct 2020 16:28:40
User entered '1'	System	02 Oct 2020 12:40:33

**US3112121**

**Folder: SAE USA-US062-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:11:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered '28/Oct/2020 13:15'	System	28 Oct 2020 17:15:42

US3112121

Folder: SAE USA-US062-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:11:31

**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.	Todd Simmons (b) (4)	02 Apr 2021 21:00:48
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 17:15:42