

US3052020 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:55:49

All time stamps listed in this document are displayed in GMT

US3052020

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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[Participant ID](#)

US3052020

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

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US3052020

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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

US3052020

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Date of Birth (MMM yyyy)	(b) (6) 1993
Age	26
Age Units	YEARS
Age (Derived)	26
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Date of Informed Consent (*dd MMM yyyy*) 30 JUL 2020

Month and Year of Informed Consent (derived) JUL 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

US3052020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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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) 23 Feb 2021 07:46:38

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Mar 2021 16:34:35

Generated On: 11 Aug 2021 21:55:49

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Mar 2021 16:34:35

Generated On: 11 Aug 2021 21:55:49

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

US3052020

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Mar 2021 16:34:35

Generated On: 11 Aug 2021 21:55:49

Condition	ANXIETY
Start date (dd MMM yyyy)	26 AUG 2019
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)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 JUL 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 14:55
Height (xxx.x)	64 in
Weight (xxx.x)	128 lb
BMI (xxx.x)	22.01709 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 JUL 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 07:46:37

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Date of assessment (dd MMM yyyy) 30 JUL 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	30 JUL 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3052020

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 07:46:38

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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**

STAY AT HOME MOM

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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) 23 Feb 2021 07:46:38

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 JUL 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) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

What was the date of randomization? (dd MMM yyyy) 30 JUL 2020

What was the participant's randomization number? 142393

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) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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)	30 JUL 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 14:45
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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)	30 JUL 2020
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 16:15
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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) 30 JUL 2020

What was the treatment time? (00:00-23:59) 15:42 (24 HR)

Treatment Date and Time (derived) 30 JUL 2020 15:42

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) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 JUL 2020
Collection time (00:00-23:59)	15:30 (24 HR)
Collection date and time (derived)	30 JUL 2020 15:30

US3052020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Collection date (dd MMM yyyy)			30 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:36	30 JUL 2020 15:36
Nasopharyngeal Swab 2	No		

US3052020

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 16:20

PC Open Date & Time

30 JUL 2020 16:02

PC Close Date & Time

30 JUL 2020 18:32

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**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	30 JUL 2020 19:38
PC Open Date & Time	30 JUL 2020 19:27
PC Close Date & Time	31 JUL 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °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

31 JUL 2020 22:11

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

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

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	01 AUG 2020 20:51
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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**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.

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.8 °F

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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 AUG 2020 14:06

---

PC Open Date & Time

02 AUG 2020 12:00

---

PC Close Date & Time

03 AUG 2020 11:59

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US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 17:59

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 22:19

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.8 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

05 AUG 2020 16:18

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PC Open Date & Time

05 AUG 2020 12:00

---

PC Close Date & Time

06 AUG 2020 11:59

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US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**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

30 JUL 2020 16:20

PC Open Date & Time

30 JUL 2020 16:02

PC Close Date & Time

30 JUL 2020 18:32

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**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

30 JUL 2020 19:39

PC Open Date & Time

30 JUL 2020 19:27

PC Close Date & Time

31 JUL 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**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

31 JUL 2020 22:11

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**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

01 AUG 2020 20:51

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**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

02 AUG 2020 14:06

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59



US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**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

03 AUG 2020 17:59

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**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

04 AUG 2020 22:19

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 16:19

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**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 ☐

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 16:21
PC Open Date & Time	30 JUL 2020 16:02
PC Close Date & Time	30 JUL 2020 18:32

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**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 ☐

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 19:39
PC Open Date & Time	30 JUL 2020 19:27
PC Close Date & Time	31 JUL 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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 ☒



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 22:12
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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49 of 1726

EAB) (1725)

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 20:52
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**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 ☒

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 14:06
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

53 of 1726

EAB) (1725)

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 17:59
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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 ☒



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 22:20
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 16:19
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3052020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052020

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052020

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3052020

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	VISIT2

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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)	26 AUG 2020
Time of assessment (00:00-23:59)	11:57 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:57
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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

US3052020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3052020

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 26 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 12:30 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 12:30

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

US3052020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	12:19 (24 HR)
Collection date and time (derived)	26 AUG 2020 12:19



US3052020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:15	26 AUG 2020 12:15
Nasopharyngeal Swab 2	No		

US3052020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**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

98.2 °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

26 AUG 2020 13:06

PC Open Date & Time

26 AUG 2020 12:50

PC Close Date & Time

26 AUG 2020 15:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**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 97.3 °F

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

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

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

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

PC Time Stamp 26 AUG 2020 16:27

PC Open Date & Time 26 AUG 2020 16:15

PC Close Date & Time 27 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

27 AUG 2020 20:44

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

29 AUG 2020 07:47

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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**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

29 AUG 2020 21:26

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**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

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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**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

98.8 °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

31 AUG 2020 22:32

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 16:34

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**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

26 AUG 2020 13:07

PC Open Date & Time

26 AUG 2020 12:50

PC Close Date & Time

26 AUG 2020 15:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**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

26 AUG 2020 16:28

PC Open Date & Time

26 AUG 2020 16:15

PC Close Date & Time

27 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**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

27 AUG 2020 20:44

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**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

29 AUG 2020 07:47

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**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

29 AUG 2020 21:26

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**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

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**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

31 AUG 2020 22:32

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**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

01 SEP 2020 16:34

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**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 ☐

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 13:07
PC Open Date & Time	26 AUG 2020 12:50
PC Close Date & Time	26 AUG 2020 15:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**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 ☐

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 16:29
PC Open Date & Time	26 AUG 2020 16:15
PC Close Date & Time	27 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**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 ☒

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:44
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**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 ☒

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 07:47
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**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 ☒

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:26
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

Yes ☐

PC Time stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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 ☒

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 22:32
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**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 ☒

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 16:34
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3052020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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

US3052020

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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

US3052020

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

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*

US3052020

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3052020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	VISIT3

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:52
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3052020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	11:25 (24 HR)
Collection date and time (derived)	30 SEP 2020 11:25

US3052020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2020 00:01

Patient Cloud Close Date & Time

03 OCT 2020 23:59

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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 <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"/>



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 OCT 2020 10:19:38
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

10 NOV 2020 00:11:00

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 00:14:37

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

07 DEC 2020 12:14:06

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2020 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

19 DEC 2020 13:44:03

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	20 JAN 2021 17:24:51
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

26 JAN 2021 18:00:05

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 187

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 00:02:46

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

13 FEB 2021 14:15:51

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

20 FEB 2021 00:02:22

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 19:25:04

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

06 MAR 2021 07:07:36

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

13 MAR 2021 18:03:47

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 00:01:26

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 00:36:31

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

10 APR 2021 07:11:35

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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 <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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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

26 APR 2021 19:55:38

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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 <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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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 <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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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="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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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="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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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 <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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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="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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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 <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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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 <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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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="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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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11 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 DEC 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	01 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JAN 2022 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JAN 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 621

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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="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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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 <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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2022 23:59



US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**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 ☐

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3052020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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="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"/>

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	01 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59

US3052020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:55:49

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		03 MAR 2021 19:24:55

US3052020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3052020

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052020

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052020

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 14:46:38

Generated On: 11 Aug 2021 21:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052020

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 14:46:38

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 13:23:57

Generated On: 11 Aug 2021 21:55:49

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT4



US3052020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 13:23:57

Generated On: 11 Aug 2021 21:55:49

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

US3052020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 13:23:57

Generated On: 11 Aug 2021 21:55:49

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.*

US3052020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 13:23:57

Generated On: 11 Aug 2021 21:55:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3052020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:23:34

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 13:23:34

Generated On: 11 Aug 2021 21:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052020

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 13:23:34

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052020

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:35:02

Generated On: 11 Aug 2021 21:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052020

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:35:02

Generated On: 11 Aug 2021 21:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3052020**

**Folder: Safety Call Day 299 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

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*

**US3052020**

**Folder: Safety Call Day 299 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3052020**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Data signed:** (b) (4) 23 Feb 2021 07:46:38

**Generated On: 11 Aug 2021 21:55:49**

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>

**US3052020**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Data signed: (b) (4) 23 Feb 2021 07:46:38**

**Generated On: 11 Aug 2021 21:55:49**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3052020

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 13:23:34

Generated On: 11 Aug 2021 21:55:49

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID UNBLND\_DECIDE

US3052020

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

Form: Unblinding

Generated On: 11 Aug 2021 21:55:49

Date of updated informed consent (*dd MMM yyyy*)

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

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*)

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

US3052020

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 15:18:30

Generated On: 11 Aug 2021 21:55:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3052020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 07 Apr 2021 15:18:30

Generated On: 11 Aug 2021 21:55:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)



US3052020

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 07:46:37

Generated On: 11 Aug 2021 21:55:49

---

Did the participant experience any adverse events?

Yes ☐

No ☒

---

If Yes, enter details on the Adverse Events form.

---

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Mar 2021 16:34:35

Generated On: 11 Aug 2021 21:55:49

---

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

Yes ☒

No ☐

---

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

---

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 20:19:01

Generated On: 11 Aug 2021 21:55:49

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 37.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

338 of 1726

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 20:19:01

Generated On: 11 Aug 2021 21:55:49

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

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 20:19:01

Generated On: 11 Aug 2021 21:55:49

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE AFTER 2ND  
INJECTION

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

340 of 1726

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 20:19:01

Generated On: 11 Aug 2021 21:55:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3052020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3052020

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 23 Feb 2021 07:46:38

Generated On: 11 Aug 2021 21:55:49

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>



Audit

US3052020 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

**US3052020**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:55:49**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'US3052020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:14:15

US3052020

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	amy sheets (b) (4)	30 Jul 2020 20:14:53

**US3052020**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:14:17

**US3052020**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Clinic (Clinic)'	amy sheets (b) (4)	30 Jul 2020 20:14:53

**US3052020**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'SCRN'	System	30 Jul 2020 20:14:53

US3052020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered (b) (6) 1993'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:14:17

US3052020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4)	08 Oct 2020 09:05:28
Query 'Per CDM: Please complete this form.' answered with 'Completed.' (Site from DM).	Avia McClain-Stocker	07 Oct 2020 20:35:10
User entered '26'	(b) (4)	02 Sep 2020 18:35:06
User opened query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 11:16:13



**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'YEARS'	System	02 Sep 2020 18:35:06

**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered '26'	System	30 Jul 2020 20:15:22

**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Female (F)'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

US3052020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'I'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

US3052020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06



**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

US3052020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:55:49

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

**US3052020**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:55:49**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Nicole Davis (b) (4)	02 Sep 2020 18:35:06

US3052020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	amy sheets (b) (4)	30 Jul 2020 20:15:22

**US3052020**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'Jul 2020'	System	30 Jul 2020 20:15:22

**US3052020**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered '2020'	System	30 Jul 2020 20:15:22



US3052020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Amendment 1 (1)'	amy sheets (b) (4)	30 Jul 2020 20:15:22

US3052020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	amy sheets (b) (4)	30 Jul 2020 20:15:22

**US3052020**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	amy sheets (b) (4)	30 Jul 2020 20:15:22

US3052020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	amy sheets (b) (4)	30 Jul 2020 20:15:22

US3052020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	amy sheets (b) (4)	30 Jul 2020 20:15:22

**US3052020**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:55:49**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:14:17

US3052020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:55:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'I'	System	30 Jul 2020 20:15:27

US3052020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	amy sheets (b) (4)	30 Jul 2020 20:15:27



US3052020

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:55:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 12:10:03
User entered 'No (N)'	Avia McClain-Stocker	06 Oct 2020 15:55:58
	(b) (4)	

US3052020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 12:11:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 12:11:21
Data point term sent to Coder	System	09 Oct 2020 12:10:33
User entered 'Appendectomy'	Avia McClain-Stocker	09 Oct 2020 12:10:29
	(b) (4)	

**US3052020**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'un UNK 2014'	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:29

**US3052020**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:29

**US3052020**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:29

**US3052020**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:55:49**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'un UNK 2014'	(b) (4) Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:29

**US3052020**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:29

**US3052020**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'Jan 2014'	System	09 Oct 2020 12:10:29



**US3052020**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered '2014'	System	09 Oct 2020 12:10:29

**US3052020**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'Jan 2014'	System	09 Oct 2020 12:10:29

**US3052020**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered '2014'	System	09 Oct 2020 12:10:29

US3052020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 12:12:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 12:12:24
Data point term sent to Coder	System	09 Oct 2020 12:11:33
User entered 'Tonsilectomy'	Avia McClain-Stocker	09 Oct 2020 12:10:53
	(b) (4)	

US3052020

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'un UNK 2006'	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:53

**US3052020**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:53

**US3052020**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:53

**US3052020**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'un UNK 2006'	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:53



**US3052020**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:10:53

**US3052020**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'Jan 2006'	System	09 Oct 2020 12:10:53

**US3052020**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered '2006'	System	09 Oct 2020 12:10:53

**US3052020**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'Jan 2006'	System	09 Oct 2020 12:10:53

**US3052020**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered '2006'	System	09 Oct 2020 12:10:53

US3052020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 15:56:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 15:56:46
Data point term sent to Coder	System	17 Mar 2021 15:56:14
User entered 'ANXIETY'	(b) (4), (b) (6)	17 Mar 2021 15:55:17

US3052020

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	17 Mar 2021 15:56:55
User entered '26 Aug 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 15:56:55
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	17 Mar 2021 15:55:17
User entered '26 Aug 2020'	(b) (4), (b) (6)	17 Mar 2021 15:55:17

**US3052020**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:55:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:55:17



**US3052020**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:55:49**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:55:17

**US3052020**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:55:17

**US3052020**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:55:49**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:55:17

**US3052020**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'Aug 2019'	System	17 Mar 2021 15:56:55
User entered 'Aug 2020'	System	17 Mar 2021 15:55:17

**US3052020**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered '2019'	System	17 Mar 2021 15:56:55
User entered '2020'	System	17 Mar 2021 15:55:17

**US3052020**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered empty.	System	17 Mar 2021 15:55:17

**US3052020**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered empty.	System	17 Mar 2021 15:55:17

US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4)	08 Oct 2020 07:49:27
Query 'Per CDM: Please complete this form.' answered with 'Completed' (Site from DM).	Avia McClain-Stocker	07 Oct 2020 20:36:10
User entered 'Yes (Y)'	(b) (4)	28 Sep 2020 15:13:15
User opened query 'Per CDM: Please complete this form.' (Site from DM).	Stacey Saldua (b) (4)	18 Aug 2020 11:16:41



**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	Stacey Saldua (b) (4)	28 Sep 2020 15:13:15

**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '14:55'	Stacey Saldua (b) (4)	28 Sep 2020 15:13:15

**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered '30 Jul 2020 14:55'	System	28 Sep 2020 15:13:15

US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '64' in	(b) (4) Stacey Saldua (b) (4)	28 Sep 2020 15:13:15
DataPoint set to visible.	(b) (4) System	30 Jul 2020 20:15:27

US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '128' lb	(b) (4) Stacey Saldua (b) (4)	28 Sep 2020 15:13:15
DataPoint set to visible.	(b) (4) System	30 Jul 2020 20:15:27

**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered '22.01709'	System	28 Sep 2020 15:13:15
DataPoint set to visible.	System	30 Jul 2020 20:15:27

**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'kg/m2'	System	28 Sep 2020 15:13:15
DataPoint set to visible.	System	30 Jul 2020 20:15:27

US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:02
User entered '98.1' F	Stacey Saldua (b) (4)	28 Sep 2020 15:13:15
	(b) (4)	



US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty; reason for change Data Entry Error	(b) (4) Avia McClain-Stocker	09 Oct 2020 12:47:56
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4)	28 Sep 2020 15:13:15

US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:13:15

US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:02
User entered '79'	Stacey Saldua (b) (4)	28 Sep 2020 15:13:15
	(b) (4)	

**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'bpm'	System	28 Sep 2020 15:13:15

US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:02
User entered '12'	Stacey Saldua (b) (4)	28 Sep 2020 15:13:15
	(b) (4)	

**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'breaths/min'	System	28 Sep 2020 15:13:15

US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:02
User entered '134'	Avia McClain-Stocker (b) (4)	28 Sep 2020 15:13:15
	(b) (4)	

**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'mmHg'	System	28 Sep 2020 15:13:15



US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:02
User entered '90'	Stacey Saldua (b) (4)	28 Sep 2020 15:13:15
	(b) (4)	

**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered 'mmHg'	System	28 Sep 2020 15:13:15

US3052020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43

**US3052020**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43

**US3052020**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:55:49**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Sep 2020 15:15:47

**US3052020**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	Stacey Saldua (b) (4)	28 Sep 2020 15:15:47

**US3052020**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	Stacey Saldua (b) (4)	28 Sep 2020 15:25:59

US3052020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Sep 2020 15:25:59



US3052020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	Stacey Saldua (b) (4)	28 Sep 2020 15:25:59

US3052020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:55:49

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	Stacey Saldua (b) (4)	28 Sep 2020 15:25:59

**US3052020**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	Stacey Saldua (b) (4)	28 Sep 2020 15:25:59

**US3052020**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:55:49**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Stacey Saldua (b) (4)	28 Sep 2020 15:25:59

US3052020

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	Stacey Saldua (b) (4)	28 Sep 2020 15:25:59

**US3052020**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:55:49**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Stacey Saldua (b) (4)	28 Sep 2020 15:25:59

US3052020

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Sep 2020 15:29:21

**US3052020**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	Stacey Saldua (b) (4)	28 Sep 2020 15:29:21



**US3052020**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:55:49**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Urine (URINE)'	Stacey Saldua (b) (4)	28 Sep 2020 15:29:21

**US3052020**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:55:49**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Negative (NEGATIVE)'	(b) (4) Stacey Saldua (b) (4)	28 Sep 2020 15:29:21

US3052020

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Sep 2020 15:29:21

**US3052020**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:55:49**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	Stacey Saldua (b) (4)	28 Sep 2020 15:29:21

**US3052020**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:55:49**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	Stacey Saldua (b) (4)	28 Sep 2020 15:29:21

**US3052020**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User entered empty.	System	28 Sep 2020 15:29:21

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 14:57:37



US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

[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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37



US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Stay at home mom'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	07 Oct 2020 20:38:22
User entered '0' reason for change: Data Entry Error	Avia McClain-Stocker	07 Oct 2020 20:38:22
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	28 Sep 2020 14:57:37
User entered '1'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

[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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

**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)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37



US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'I'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '0'	Stacey Saldua (b) (4)	28 Sep 2020 14:57:37

US3052020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:55:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:59:43
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Sep 2020 14:57:37
	(b) (4)	

US3052020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:34:25

US3052020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:34:25

US3052020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Clinic (Clinic)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:34:25

US3052020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'VISIT1'	System	28 Sep 2020 15:34:25

US3052020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:19:09



US3052020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:49

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:24:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:24:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Jul 2020 19:19:09
User entered '142393' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:19:09

US3052020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 08:40:57
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'Per source documentation, patient is not at risk. Stratification error. ' (Site from System).	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:05:15
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:04:55
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:19:09

US3052020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:49

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)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 08:41:01
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Reviewed and completed. ' (Site from DM).	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:05:24
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	07 Oct 2020 20:04:55
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 13:34:06

US3052020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:49

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)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	07 Oct 2020 20:04:55

US3052020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	07 Oct 2020 20:04:55

US3052020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:49

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	07 Oct 2020 20:04:55

US3052020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:55:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	07 Oct 2020 20:04:55

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:26
User entered '66' in	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52



US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:49

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:26
User entered '128' lb	Avia McClain-Stocker	06 Oct 2020 16:00:52
	(b) (4)	

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:26
User entered '66' in	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:49

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:26
User entered '128' lb	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User accepted default value 'Pre-Dose (PREDOSE)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

**US3052020**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '14:45'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '30 Jul 2020 14:45'	System	06 Oct 2020 16:00:52



US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '98.1' F	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '79'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'bpm'	System	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '12'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'breaths/min'	System	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '134'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52



US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'mmHg'	System	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '90'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'mmHg'	System	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:26
User entered '66' in	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:55:49

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	07 Oct 2020 20:36:26
User entered '128' lb	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User accepted default value 'Post-Dose (POSTDOSE)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52



US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '16:15'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '30 Jul 2020 16:15'	System	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '99' F	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '75'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

**US3052020**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 21:55:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'bpm'	System	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '20'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52



US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'breaths/min'	System	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '118'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'mmHg'	System	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '73'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'mmHg'	System	06 Oct 2020 16:00:52

US3052020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 12:48:21
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Sep 2020 15:35:45
	(b) (4)	

US3052020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty; reason for change Data Entry Error	(b) (4)	
	Avia McClain-Stocker	09 Oct 2020 12:48:21
	(b) (4)	
User entered '30 Jul 2020'	Stacey Saldua (b) (4)	28 Sep 2020 15:35:45
	(b) (4)	

US3052020

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4), (b) (6)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
Query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 08:58:11
User closed query 'Per CDM: As Per CCG, If Screening and dosing are done on the same day. Pregnancy test page should be marked as 'No' at VID1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:57:24
Query 'Per CDM: As Per CCG, If Screening and dosing are done on the same day. Pregnancy test page should be marked as 'No' at VID1. Please update accordingly' answered with 'updated' (Site from DM).	Avia McClain-Stocker (b) (4)	08 Oct 2020 13:32:27
User opened query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	08 Oct 2020 13:32:20
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	08 Oct 2020 13:32:20
User opened query 'Per CDM: As Per CCG, If Screening and dosing are done on the same day. Pregnancy test page should be marked as 'No' at VID1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:13:52
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:38:53



US3052020

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty; reason for change Data Entry Error	(b) (4)	
	Avia McClain-Stocker	08 Oct 2020 13:32:20
	(b) (4)	
User entered '30 Jul 2020'	Stacey Saldua (b) (4)	28 Sep 2020 15:38:53
	(b) (4)	

US3052020

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'Per CDM : Kindly remove the test performed and result. Thanks ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 09:01:08
Query 'Per CDM : Kindly remove the test performed and result. Thanks ' answered with 'updated.' (Site from DM).	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:48:39
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	09 Oct 2020 12:48:34
User opened query 'Per CDM : Kindly remove the test performed and result. Thanks ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:58:07
User entered 'Urine (URINE)'	Stacey Saldua (b) (4)	28 Sep 2020 15:38:53

US3052020

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty; reason for change Data Entry Error	(b) (4)	
	Avia McClain-Stocker	09 Oct 2020 12:48:34
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Stacey Saldua (b) (4)	28 Sep 2020 15:38:53
	(b) (4)	

US3052020

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:38:53

US3052020

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:38:53

US3052020

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:38:53

**US3052020**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered empty.	System	28 Sep 2020 15:38:53

US3052020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 20:16:04



US3052020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 20:16:04

US3052020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

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)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 20:16:04

US3052020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'MRNA-1273 OR PLACEBO'	System	30 Jul 2020 20:16:04

US3052020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 20:16:04

US3052020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '15:42'	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 20:16:04

**US3052020**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:55:49**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '30 Jul 2020 15:42'	System	30 Jul 2020 20:16:04

US3052020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Left Arm (LEFT ARM)'	(b) (4) amy sheets (b) (4) (b) (4)	30 Jul 2020 20:16:04

US3052020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'ONCE'	System	30 Jul 2020 20:16:04



US3052020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'INTRAMUSCULAR'	System	30 Jul 2020 20:16:04

US3052020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:26

US3052020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:26

US3052020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '15:30'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:26

**US3052020**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '30 Jul 2020 15:30'	System	06 Oct 2020 16:01:26

US3052020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:55:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Jul 2020'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:56

US3052020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:56

US3052020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:56



US3052020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '15:36'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:56

**US3052020**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '30 Jul 2020 15:36'	System	06 Oct 2020 16:01:56

US3052020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:56

US3052020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:56

US3052020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	06 Oct 2020 16:01:56

**US3052020**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered empty.	System	06 Oct 2020 16:01:56

US3052020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:42:16

US3052020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	26 Aug 2020 16:42:16



US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:19:57', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4e85d1e9-76f1-45bd-8380-697ad4aa7812'	System	30 Jul 2020 20:17:09
User entered 'Yes (Y)'	System	30 Jul 2020 20:17:09

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:02', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4e85d1e9-76f1-45bd-8380-697ad4aa7812'	System	30 Jul 2020 20:17:09
User entered '99.0'	System	30 Jul 2020 20:17:09

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:20:02
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:06', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4e85d1e9-76f1-45bd-8380-697ad4aa7812'	System	30 Jul 2020 20:17:09
User entered 'No (N)'	System	30 Jul 2020 20:17:09

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:10', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4e85d1e9-76f1-45bd-8380-697ad4aa7812'	System	30 Jul 2020 20:17:09
User entered '30 Jul 2020 16:20'	System	30 Jul 2020 20:17:09

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Jul 2020 16:02'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Jul 2020 18:32'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:20:02
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 20:16:04



US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:38:25', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8499fdf9-b14b-4873-9113-a7c6412fba8a'	System	30 Jul 2020 23:35:36
User entered 'Yes (Y)'	System	30 Jul 2020 23:35:36

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:38:32', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8499fdf9-b14b-4873-9113-a7c6412fba8a'	System	30 Jul 2020 23:35:36
User entered '98.2'	System	30 Jul 2020 23:35:36

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:38:35', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8499fdf9-b14b-4873-9113-a7c6412fba8a'	System	30 Jul 2020 23:35:36
User entered 'No (N)'	System	30 Jul 2020 23:35:36

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:38:38', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8499fdf9-b14b-4873-9113-a7c6412fba8a'	System	30 Jul 2020 23:35:36
User entered '30 Jul 2020 19:38'	System	30 Jul 2020 23:35:36

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Jul 2020 19:27'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 2'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4bd2fd55-a061-40fb-aac4-b35d7b4d630d'	System	01 Aug 2020 02:08:08
User entered 'Yes (Y)'	System	01 Aug 2020 02:08:08



US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:05', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4bd2fd55-a061-40fb-aac4-b35d7b4d630d'	System	01 Aug 2020 02:08:08
User entered '99.2'	System	01 Aug 2020 02:08:08

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:07', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4bd2fd55-a061-40fb-aac4-b35d7b4d630d'	System	01 Aug 2020 02:08:08
User entered 'No (N)'	System	01 Aug 2020 02:08:08

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:10', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4bd2fd55-a061-40fb-aac4-b35d7b4d630d'	System	01 Aug 2020 02:08:08
User entered '31 Jul 2020 22:11'	System	01 Aug 2020 02:08:08

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 3'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:10', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '71aff18c-f232-4c31-8de4-e1fc06480140'	System	02 Aug 2020 00:48:28
User entered 'Yes (Y)'	System	02 Aug 2020 00:48:28

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:16', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '71aff18c-f232-4c31-8de4-e1fc06480140'	System	02 Aug 2020 00:48:28
User entered '98.2'	System	02 Aug 2020 00:48:28



US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:22', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '71aff18c-f232-4c31-8de4-e1fc06480140'	System	02 Aug 2020 00:48:28
User entered 'Yes (Y)'	System	02 Aug 2020 00:48:28

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject contacted. Unsure of what was taken' (Site from System).		10 Nov 2020 04:29:12
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject contacted. Unsure of what was taken' (Site from System).	Avia McClain-Stocker (b) (4)	09 Nov 2020 13:05:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	02 Aug 2020 00:48:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:27', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '71aff18c-f232-4c31-8de4-e1fc06480140'	System	02 Aug 2020 00:48:28
User entered '1'	System	02 Aug 2020 00:48:28

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:27', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '71aff18c-f232-4c31-8de4-e1fc06480140'	System	02 Aug 2020 00:48:28
User entered '0'	System	02 Aug 2020 00:48:28

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:30', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '71aff18c-f232-4c31-8de4-e1fc06480140'	System	02 Aug 2020 00:48:28
User entered '01 Aug 2020 20:51'	System	02 Aug 2020 00:48:28

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 4'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:05:30', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '72b99461-f75a-41b4-8da9-ea939306b6b3'	System	02 Aug 2020 18:03:04
User entered 'Yes (Y)'	System	02 Aug 2020 18:03:04



US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:04', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '72b99461-f75a-41b4-8da9-ea939306b6b3'	System	02 Aug 2020 18:03:04
User entered '98.8'	System	02 Aug 2020 18:03:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:06', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '72b99461-f75a-41b4-8da9-ea939306b6b3'	System	02 Aug 2020 18:03:04
User entered 'No (N)'	System	02 Aug 2020 18:03:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:08', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '72b99461-f75a-41b4-8da9-ea939306b6b3'	System	02 Aug 2020 18:03:04
User entered '02 Aug 2020 14:06'	System	02 Aug 2020 18:03:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 5'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:58:32', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b030beda-8b64-48a9-bd00-88342c07326b'	System	03 Aug 2020 21:56:19
User entered 'Yes (Y)'	System	03 Aug 2020 21:56:19

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:19', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b030beda-8b64-48a9-bd00-88342c07326b'	System	03 Aug 2020 21:56:19
User entered '98.3'	System	03 Aug 2020 21:56:19



US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:21', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b030beda-8b64-48a9-bd00-88342c07326b'	System	03 Aug 2020 21:56:19
User entered 'No (N)'	System	03 Aug 2020 21:56:19

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:20:02
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:23', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b030beda-8b64-48a9-bd00-88342c07326b'	System	03 Aug 2020 21:56:19
User entered '03 Aug 2020 17:59'	System	03 Aug 2020 21:56:19

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:20:02
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 6'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:34', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1690e643-8f02-4b00-8b6e-3ac93a23dd21'	System	05 Aug 2020 02:16:37
User entered 'Yes (Y)'	System	05 Aug 2020 02:16:37

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:39', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1690e643-8f02-4b00-8b6e-3ac93a23dd21'	System	05 Aug 2020 02:16:37
User entered '99.1'	System	05 Aug 2020 02:16:37

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:41', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1690e643-8f02-4b00-8b6e-3ac93a23dd21'	System	05 Aug 2020 02:16:37
User entered 'No (N)'	System	05 Aug 2020 02:16:37



US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:43', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1690e643-8f02-4b00-8b6e-3ac93a23dd21'	System	05 Aug 2020 02:16:37
User entered '04 Aug 2020 22:19'	System	05 Aug 2020 02:16:37

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:20:02
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 7'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:18:37', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e4be7b46-84e1-45ef-82b5-876727076638'	System	05 Aug 2020 20:15:43
User entered 'Yes (Y)'	System	05 Aug 2020 20:15:43

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:18:44', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e4be7b46-84e1-45ef-82b5-876727076638'	System	05 Aug 2020 20:15:43
User entered '98.8'	System	05 Aug 2020 20:15:43

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:18:46', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e4be7b46-84e1-45ef-82b5-876727076638'	System	05 Aug 2020 20:15:43
User entered 'No (N)'	System	05 Aug 2020 20:15:43

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:18:48', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e4be7b46-84e1-45ef-82b5-876727076638'	System	05 Aug 2020 20:15:43
User entered '05 Aug 2020 16:18'	System	05 Aug 2020 20:15:43



US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:02
Data hard locked.		25 Feb 2021 15:10:15
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:17', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'c7acacde-be83-4fe9-a5d3-b07c0824e191'	System	30 Jul 2020 20:17:40
User entered 'None (1)'	System	30 Jul 2020 20:17:40

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:29', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'c7acacde-be83-4fe9-a5d3-b07c0824e191'	System	30 Jul 2020 20:17:40
User entered 'No (N)'	System	30 Jul 2020 20:17:40

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:34', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'c7acacde-be83-4fe9-a5d3-b07c0824e191'	System	30 Jul 2020 20:17:40
User entered 'No (N)'	System	30 Jul 2020 20:17:40

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:37', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'c7acacde-be83-4fe9-a5d3-b07c0824e191'	System	30 Jul 2020 20:17:40
User entered 'None (1)'	System	30 Jul 2020 20:17:40

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:40', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'c7acacde-be83-4fe9-a5d3-b07c0824e191'	System	30 Jul 2020 20:17:40
User entered '30 Jul 2020 16:20'	System	30 Jul 2020 20:17:40



**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Jul 2020 16:02'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Jul 2020 18:32'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:20:10
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:38:45', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b08995b-9dad-405e-bc17-7859546d71f3'	System	30 Jul 2020 23:36:07
User entered 'None (1)'	System	30 Jul 2020 23:36:07

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b08995b-9dad-405e-bc17-7859546d71f3'	System	30 Jul 2020 23:36:07
User entered 'No (N)'	System	30 Jul 2020 23:36:07

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:03', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b08995b-9dad-405e-bc17-7859546d71f3'	System	30 Jul 2020 23:36:07
User entered 'No (N)'	System	30 Jul 2020 23:36:07

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:06', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b08995b-9dad-405e-bc17-7859546d71f3'	System	30 Jul 2020 23:36:07
User entered 'None (1)'	System	30 Jul 2020 23:36:07

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:09', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b08995b-9dad-405e-bc17-7859546d71f3'	System	30 Jul 2020 23:36:07
User entered '30 Jul 2020 19:39'	System	30 Jul 2020 23:36:07



US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Jul 2020 19:27'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 2'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:16', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7facac4d-1bac-492e-9c2f-274c0422fd86'	System	01 Aug 2020 02:08:29
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 02:08:29

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:19', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7facac4d-1bac-492e-9c2f-274c0422fd86'	System	01 Aug 2020 02:08:29
User entered 'No (N)'	System	01 Aug 2020 02:08:29

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:24', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7facac4d-1bac-492e-9c2f-274c0422fd86'	System	01 Aug 2020 02:08:29
User entered 'No (N)'	System	01 Aug 2020 02:08:29

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:27', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7facac4d-1bac-492e-9c2f-274c0422fd86'	System	01 Aug 2020 02:08:29
User entered 'None (1)'	System	01 Aug 2020 02:08:29

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:31', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7facac4d-1bac-492e-9c2f-274c0422fd86'	System	01 Aug 2020 02:08:29
User entered '31 Jul 2020 22:11'	System	01 Aug 2020 02:08:29



US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 3'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:34', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b28c2803-d912-45ac-a929-f72839fe2191'	System	02 Aug 2020 00:48:38
User entered 'None (1)'	System	02 Aug 2020 00:48:38

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:36', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b28c2803-d912-45ac-a929-f72839fe2191'	System	02 Aug 2020 00:48:38
User entered 'No (N)'	System	02 Aug 2020 00:48:38

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:38', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b28c2803-d912-45ac-a929-f72839fe2191'	System	02 Aug 2020 00:48:38
User entered 'No (N)'	System	02 Aug 2020 00:48:38

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:40', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b28c2803-d912-45ac-a929-f72839fe2191'	System	02 Aug 2020 00:48:38
User entered 'None (1)'	System	02 Aug 2020 00:48:38

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:42', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b28c2803-d912-45ac-a929-f72839fe2191'	System	02 Aug 2020 00:48:38
User entered '01 Aug 2020 20:51'	System	02 Aug 2020 00:48:38



US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 4'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:12', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '42de55f0-b76e-4808-ba4f-282019d3bc6b'	System	02 Aug 2020 18:03:14
User entered 'None (1)'	System	02 Aug 2020 18:03:14

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:13', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '42de55f0-b76e-4808-ba4f-282019d3bc6b'	System	02 Aug 2020 18:03:14
User entered 'No (N)'	System	02 Aug 2020 18:03:14

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:15', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '42de55f0-b76e-4808-ba4f-282019d3bc6b'	System	02 Aug 2020 18:03:14
User entered 'No (N)'	System	02 Aug 2020 18:03:14

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:16', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '42de55f0-b76e-4808-ba4f-282019d3bc6b'	System	02 Aug 2020 18:03:14
User entered 'None (1)'	System	02 Aug 2020 18:03:14

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:18', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '42de55f0-b76e-4808-ba4f-282019d3bc6b'	System	02 Aug 2020 18:03:14
User entered '02 Aug 2020 14:06'	System	02 Aug 2020 18:03:14



US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:20:10
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 5'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:26', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd12590fb-f611-4419-8ab8-2c2825a453ac'	System	03 Aug 2020 21:56:31
User entered 'None (1)'	System	03 Aug 2020 21:56:31

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:28', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd12590fb-f611-4419-8ab8-2c2825a453ac'	System	03 Aug 2020 21:56:31
User entered 'No (N)'	System	03 Aug 2020 21:56:31

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:30', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd12590fb-f611-4419-8ab8-2c2825a453ac'	System	03 Aug 2020 21:56:31
User entered 'No (N)'	System	03 Aug 2020 21:56:31

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:32', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd12590fb-f611-4419-8ab8-2c2825a453ac'	System	03 Aug 2020 21:56:31
User entered 'None (1)'	System	03 Aug 2020 21:56:31

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:33', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd12590fb-f611-4419-8ab8-2c2825a453ac'	System	03 Aug 2020 21:56:31
User entered '03 Aug 2020 17:59'	System	03 Aug 2020 21:56:31



**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 6'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:46', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'f4e7780e-494a-4abe-88b1-0389eb26592f'	System	05 Aug 2020 02:16:47
User entered 'None (1)'	System	05 Aug 2020 02:16:47

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:48', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'f4e7780e-494a-4abe-88b1-0389eb26592f'	System	05 Aug 2020 02:16:47
User entered 'No (N)'	System	05 Aug 2020 02:16:47

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:50', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'f4e7780e-494a-4abe-88b1-0389eb26592f'	System	05 Aug 2020 02:16:47
User entered 'No (N)'	System	05 Aug 2020 02:16:47

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:51', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'f4e7780e-494a-4abe-88b1-0389eb26592f'	System	05 Aug 2020 02:16:47
User entered 'None (1)'	System	05 Aug 2020 02:16:47

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:53', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'f4e7780e-494a-4abe-88b1-0389eb26592f'	System	05 Aug 2020 02:16:47
User entered '04 Aug 2020 22:19'	System	05 Aug 2020 02:16:47



**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 7'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:18:51', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bb55691b-25b2-402c-9eec-14b6b62da1d6'	System	05 Aug 2020 20:15:59
User entered 'None (1)'	System	05 Aug 2020 20:15:59

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:18:53', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bb55691b-25b2-402c-9eec-14b6b62da1d6'	System	05 Aug 2020 20:15:59
User entered 'No (N)'	System	05 Aug 2020 20:15:59

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:18:55', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bb55691b-25b2-402c-9eec-14b6b62da1d6'	System	05 Aug 2020 20:15:59
User entered 'No (N)'	System	05 Aug 2020 20:15:59

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:18:56', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bb55691b-25b2-402c-9eec-14b6b62da1d6'	System	05 Aug 2020 20:15:59
User entered 'None (1)'	System	05 Aug 2020 20:15:59

US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:19:05', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bb55691b-25b2-402c-9eec-14b6b62da1d6'	System	05 Aug 2020 20:15:59
User entered '05 Aug 2020 16:19'	System	05 Aug 2020 20:15:59



US3052020

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:10
Data hard locked.		25 Feb 2021 15:10:15
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:44', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bf9c4d43-b8d2-44f9-87db-d557816c64bb'	System	30 Jul 2020 20:18:09
User entered 'None (0)'	System	30 Jul 2020 20:18:09

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:46', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bf9c4d43-b8d2-44f9-87db-d557816c64bb'	System	30 Jul 2020 20:18:09
User entered 'None (0)'	System	30 Jul 2020 20:18:09

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:49', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bf9c4d43-b8d2-44f9-87db-d557816c64bb'	System	30 Jul 2020 20:18:09
User entered 'None (0)'	System	30 Jul 2020 20:18:09

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:20:56', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bf9c4d43-b8d2-44f9-87db-d557816c64bb'	System	30 Jul 2020 20:18:09
User entered 'None (0)'	System	30 Jul 2020 20:18:09

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:21:02', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bf9c4d43-b8d2-44f9-87db-d557816c64bb'	System	30 Jul 2020 20:18:09
User entered 'None (0)'	System	30 Jul 2020 20:18:09



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:21:03', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bf9c4d43-b8d2-44f9-87db-d557816c64bb'	System	30 Jul 2020 20:18:09
User entered 'None (0)'	System	30 Jul 2020 20:18:09

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:21:07', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bf9c4d43-b8d2-44f9-87db-d557816c64bb'	System	30 Jul 2020 20:18:09
User entered 'No (N)'	System	30 Jul 2020 20:18:09

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T16:21:09', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bf9c4d43-b8d2-44f9-87db-d557816c64bb'	System	30 Jul 2020 20:18:09
User entered '30 Jul 2020 16:21'	System	30 Jul 2020 20:18:09

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Jul 2020 16:02'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Jul 2020 18:32'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:55:49**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:15', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6731ab8c-6605-4c04-a7bf-b0b32c2a6971'	System	30 Jul 2020 23:36:34
User entered 'None (0)'	System	30 Jul 2020 23:36:34

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:23', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6731ab8c-6605-4c04-a7bf-b0b32c2a6971'	System	30 Jul 2020 23:36:34
User entered 'None (0)'	System	30 Jul 2020 23:36:34



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:25', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6731ab8c-6605-4c04-a7bf-b0b32c2a6971'	System	30 Jul 2020 23:36:34
User entered 'None (0)'	System	30 Jul 2020 23:36:34

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:27', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6731ab8c-6605-4c04-a7bf-b0b32c2a6971'	System	30 Jul 2020 23:36:34
User entered 'None (0)'	System	30 Jul 2020 23:36:34

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:29', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6731ab8c-6605-4c04-a7bf-b0b32c2a6971'	System	30 Jul 2020 23:36:34
User entered 'None (0)'	System	30 Jul 2020 23:36:34

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:31', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6731ab8c-6605-4c04-a7bf-b0b32c2a6971'	System	30 Jul 2020 23:36:34
User entered 'None (0)'	System	30 Jul 2020 23:36:34

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:34', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6731ab8c-6605-4c04-a7bf-b0b32c2a6971'	System	30 Jul 2020 23:36:34
User entered 'No (N)'	System	30 Jul 2020 23:36:34

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-30T19:39:36', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6731ab8c-6605-4c04-a7bf-b0b32c2a6971'	System	30 Jul 2020 23:36:34
User entered '30 Jul 2020 19:39'	System	30 Jul 2020 23:36:34

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Jul 2020 19:27'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 20:16:04



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 2'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:54', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '29303ab4-2b7f-4cf2-9a97-435dd880149b'	System	01 Aug 2020 02:09:10
User entered 'None (0)'	System	01 Aug 2020 02:09:10

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:56', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '29303ab4-2b7f-4cf2-9a97-435dd880149b'	System	01 Aug 2020 02:09:10
User entered 'None (0)'	System	01 Aug 2020 02:09:10

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:11:58', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '29303ab4-2b7f-4cf2-9a97-435dd880149b'	System	01 Aug 2020 02:09:10
User entered 'None (0)'	System	01 Aug 2020 02:09:10

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:12:03', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '29303ab4-2b7f-4cf2-9a97-435dd880149b'	System	01 Aug 2020 02:09:10
User entered 'None (0)'	System	01 Aug 2020 02:09:10

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:20:20
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:12:05', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '29303ab4-2b7f-4cf2-9a97-435dd880149b'	System	01 Aug 2020 02:09:10
User entered 'None (0)'	System	01 Aug 2020 02:09:10

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:12:09', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '29303ab4-2b7f-4cf2-9a97-435dd880149b'	System	01 Aug 2020 02:09:10
User entered 'No interference with activity (1)'	System	01 Aug 2020 02:09:10

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:12:11', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '29303ab4-2b7f-4cf2-9a97-435dd880149b'	System	01 Aug 2020 02:09:10
User entered 'No (N)'	System	01 Aug 2020 02:09:10



**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-07-31T22:12:14', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '29303ab4-2b7f-4cf2-9a97-435dd880149b'	System	01 Aug 2020 02:09:10
User entered '31 Jul 2020 22:12'	System	01 Aug 2020 02:09:10

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 3'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User closed query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Subject contacted. Unsure of what was taken' (Site from DM).	Avia McClain-Stocker (b) (4)	09 Nov 2020 13:05:47
User opened query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 11:10:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:49', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '007b45ca-a021-46bc-ae69-1782ff8ba456'	System	02 Aug 2020 00:49:03
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	02 Aug 2020 00:49:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:53', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '007b45ca-a021-46bc-ae69-1782ff8ba456'	System	02 Aug 2020 00:49:03
User entered 'No interference with activity (1)'	System	02 Aug 2020 00:49:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:55', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '007b45ca-a021-46bc-ae69-1782ff8ba456'	System	02 Aug 2020 00:49:03
User entered 'None (0)'	System	02 Aug 2020 00:49:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:51:58', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '007b45ca-a021-46bc-ae69-1782ff8ba456'	System	02 Aug 2020 00:49:03
User entered 'None (0)'	System	02 Aug 2020 00:49:03



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:52:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '007b45ca-a021-46bc-ae69-1782ff8ba456'	System	02 Aug 2020 00:49:03
User entered 'None (0)'	System	02 Aug 2020 00:49:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:52:01', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '007b45ca-a021-46bc-ae69-1782ff8ba456'	System	02 Aug 2020 00:49:03
User entered 'None (0)'	System	02 Aug 2020 00:49:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:52:04', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '007b45ca-a021-46bc-ae69-1782ff8ba456'	System	02 Aug 2020 00:49:03
User entered 'No (N)'	System	02 Aug 2020 00:49:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-01T20:52:06', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '007b45ca-a021-46bc-ae69-1782ff8ba456'	System	02 Aug 2020 00:49:03
User entered '01 Aug 2020 20:52'	System	02 Aug 2020 00:49:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 4'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:21', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '54c42722-744e-4d52-a03c-dc5ab3eb3c10'	System	02 Aug 2020 18:03:30
User entered 'None (0)'	System	02 Aug 2020 18:03:30



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:23', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '54c42722-744e-4d52-a03c-dc5ab3eb3c10'	System	02 Aug 2020 18:03:30
User entered 'None (0)'	System	02 Aug 2020 18:03:30

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:25', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '54c42722-744e-4d52-a03c-dc5ab3eb3c10'	System	02 Aug 2020 18:03:30
User entered 'None (0)'	System	02 Aug 2020 18:03:30

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:27', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '54c42722-744e-4d52-a03c-dc5ab3eb3c10'	System	02 Aug 2020 18:03:30
User entered 'None (0)'	System	02 Aug 2020 18:03:30

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:29', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '54c42722-744e-4d52-a03c-dc5ab3eb3c10'	System	02 Aug 2020 18:03:30
User entered 'None (0)'	System	02 Aug 2020 18:03:30

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:31', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '54c42722-744e-4d52-a03c-dc5ab3eb3c10'	System	02 Aug 2020 18:03:30
User entered 'None (0)'	System	02 Aug 2020 18:03:30

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:33', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '54c42722-744e-4d52-a03c-dc5ab3eb3c10'	System	02 Aug 2020 18:03:30
User entered 'No (N)'	System	02 Aug 2020 18:03:30

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-02T14:06:35', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '54c42722-744e-4d52-a03c-dc5ab3eb3c10'	System	02 Aug 2020 18:03:30
User entered '02 Aug 2020 14:06'	System	02 Aug 2020 18:03:30

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 20:16:04



**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 5'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:36', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b6a9d371-ed3-440c-af2a-c42bcd6f7680'	System	03 Aug 2020 21:56:43
User entered 'None (0)'	System	03 Aug 2020 21:56:43

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:37', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b6a9d371-ed3-440c-af2a-c42bcd6f7680'	System	03 Aug 2020 21:56:43
User entered 'None (0)'	System	03 Aug 2020 21:56:43

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:38', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b6a9d371-ed3-440c-af2a-c42bcd6f7680'	System	03 Aug 2020 21:56:43
User entered 'None (0)'	System	03 Aug 2020 21:56:43

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:39', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b6a9d371-ed3-440c-af2a-c42bcd6f7680'	System	03 Aug 2020 21:56:43
User entered 'None (0)'	System	03 Aug 2020 21:56:43

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:40', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b6a9d371-ed3-440c-af2a-c42bcd6f7680'	System	03 Aug 2020 21:56:43
User entered 'None (0)'	System	03 Aug 2020 21:56:43

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:41', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b6a9d371-ed3-440c-af2a-c42bcd6f7680'	System	03 Aug 2020 21:56:43
User entered 'None (0)'	System	03 Aug 2020 21:56:43



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:43', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b6a9d371-ed3-440c-af2a-c42bcd6f7680'	System	03 Aug 2020 21:56:43
User entered 'No (N)'	System	03 Aug 2020 21:56:43

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-03T17:59:45', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b6a9d371-ed3-440c-af2a-c42bcd6f7680'	System	03 Aug 2020 21:56:43
User entered '03 Aug 2020 17:59'	System	03 Aug 2020 21:56:43

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 6'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:56', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1237e3a9-50d8-4345-b47b-4e9065ee0413'	System	05 Aug 2020 02:17:03
User entered 'None (0)'	System	05 Aug 2020 02:17:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:58', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1237e3a9-50d8-4345-b47b-4e9065ee0413'	System	05 Aug 2020 02:17:03
User entered 'None (0)'	System	05 Aug 2020 02:17:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:19:59', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1237e3a9-50d8-4345-b47b-4e9065ee0413'	System	05 Aug 2020 02:17:03
User entered 'None (0)'	System	05 Aug 2020 02:17:03



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:20:01', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1237e3a9-50d8-4345-b47b-4e9065ee0413'	System	05 Aug 2020 02:17:03
User entered 'None (0)'	System	05 Aug 2020 02:17:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:20:02', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1237e3a9-50d8-4345-b47b-4e9065ee0413'	System	05 Aug 2020 02:17:03
User entered 'None (0)'	System	05 Aug 2020 02:17:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:20:04', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1237e3a9-50d8-4345-b47b-4e9065ee0413'	System	05 Aug 2020 02:17:03
User entered 'None (0)'	System	05 Aug 2020 02:17:03

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:20:06', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1237e3a9-50d8-4345-b47b-4e9065ee0413'	System	05 Aug 2020 02:17:03
User entered 'No (N)'	System	05 Aug 2020 02:17:03

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-04T22:20:08', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1237e3a9-50d8-4345-b47b-4e9065ee0413'	System	05 Aug 2020 02:17:03
User entered '04 Aug 2020 22:20'	System	05 Aug 2020 02:17:03

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 7'	System	30 Jul 2020 20:16:04



US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:19:08', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37aacf67-25e0-4191-97d0-df7f8609fbd2'	System	05 Aug 2020 20:16:16
User entered 'None (0)'	System	05 Aug 2020 20:16:16

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:19:10', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37aacf67-25e0-4191-97d0-df7f8609fbd2'	System	05 Aug 2020 20:16:16
User entered 'None (0)'	System	05 Aug 2020 20:16:16

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:19:12', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37aacf67-25e0-4191-97d0-df7f8609fbd2'	System	05 Aug 2020 20:16:16
User entered 'None (0)'	System	05 Aug 2020 20:16:16

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:19:14', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37aacf67-25e0-4191-97d0-df7f8609fbd2'	System	05 Aug 2020 20:16:16
User entered 'None (0)'	System	05 Aug 2020 20:16:16

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:55:49**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:19:16', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37aacf67-25e0-4191-97d0-df7f8609fbd2'	System	05 Aug 2020 20:16:16
User entered 'None (0)'	System	05 Aug 2020 20:16:16

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:19:18', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37aacf67-25e0-4191-97d0-df7f8609fbd2'	System	05 Aug 2020 20:16:16
User entered 'None (0)'	System	05 Aug 2020 20:16:16

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:19:20', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37aacf67-25e0-4191-97d0-df7f8609fbd2'	System	05 Aug 2020 20:16:16
User entered 'No (N)'	System	05 Aug 2020 20:16:16

**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-05T16:19:22', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37aacf67-25e0-4191-97d0-df7f8609fbd2'	System	05 Aug 2020 20:16:16
User entered '05 Aug 2020 16:19'	System	05 Aug 2020 20:16:16



**US3052020**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 20:16:04

US3052020

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:20:20
Data hard locked.		25 Feb 2021 15:10:15
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 20:16:04

US3052020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:45:38

US3052020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '08 Aug 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:45:38

US3052020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:45:38

US3052020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:45:38

US3052020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:42:23

**US3052020**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	26 Aug 2020 16:42:23



**US3052020**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:46:58

US3052020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
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).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 08:27:45
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 with 'Confirmed contact made 17 AUG 2020' (Site from System).	Avia McClain-Stocker (b) (4)	07 Oct 2020 12:55:12
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	28 Sep 2020 15:46:58
User entered '17 Aug 2020'	Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:46:58

**US3052020**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:46:58

US3052020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 15:46:58

US3052020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:42:30

**US3052020**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	26 Aug 2020 16:42:30

US3052020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 16:05:05

US3052020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 08:47:45
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed 24 AUG first attempt call date' (Site from System).	Avia McClain-Stocker (b) (4)	08 Oct 2020 13:24:45
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Sep 2020 16:05:05
User entered '24 Aug 2020'	Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 16:05:05



US3052020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 16:05:05

US3052020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Sep 2020 16:05:05

US3052020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:42:38

**US3052020**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	26 Aug 2020 16:42:38

US3052020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:42:48

US3052020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 11:55:08
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Aug 2020 16:42:48
User entered '26 Aug 2020'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:42:48

US3052020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Clinic (Clinic)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:42:48

**US3052020**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'VISIT2'	System	26 Aug 2020 16:42:48



US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User accepted default value 'Pre-Dose (PREDOSE)'	Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '26 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

**US3052020**

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

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

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '11:57'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '26 Aug 2020 11:57'	System	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '36.7' C	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25



US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '80'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'bpm'	System	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '18'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'breaths/min'	System	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '122'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'mmHg'	System	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '78'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:09:25

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'mmHg'	System	09 Nov 2020 13:09:25



US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User accepted default value 'Post-Dose (POSTDOSE)'	Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

**US3052020**

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

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

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered empty.	System	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58



US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered empty.	System	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered empty.	System	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered empty.	System	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:10:58

US3052020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered empty.	System	09 Nov 2020 13:10:58



US3052020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:42:56

**US3052020**

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

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '26 Aug 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:42:56

US3052020

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:11:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '26 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:11:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Nov 2020 13:11:24
User entered 'Urine (URINE)' reason for change:	System	09 Nov 2020 13:11:24
Data Entry Error	Avia McClain-Stocker (b) (4)	09 Nov 2020 13:11:24
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Nov 2020 13:11:20
User entered empty.	Avia McClain-Stocker (b) (4)	09 Nov 2020 13:11:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Negative (NEGATIVE)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:11:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:11:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:11:20



US3052020

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:55:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:11:20

**US3052020**

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

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered empty.	System	09 Nov 2020 13:11:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:43:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4)	
	Nicole Davis (b) (4)	26 Aug 2020 16:43:20
	(b) (4)	

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

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)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:43:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 16:43:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '26 Aug 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:43:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '12:30'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:43:20



US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '26 Aug 2020 12:30'	System	26 Aug 2020 16:43:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:43:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'ONCE'	System	26 Aug 2020 16:43:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:55:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 16:43:20

US3052020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:43:36

US3052020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 26AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:27:38
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 26AUG2020; however, it has not been received by GCL. Please clarify.' answered with 'Collection was shipped.' (Site from DM).	Avia McClain-Stocker (b) (4)	08 Oct 2020 13:33:32
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 26AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 16:03:57
User entered '26 Aug 2020'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:43:36

US3052020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '12:19'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:43:36

US3052020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '26 Aug 2020 12:19'	System	26 Aug 2020 16:43:36



US3052020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:55:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '26 Aug 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:44:09

US3052020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:44:09

US3052020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:44:09

**US3052020**

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

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '12:15'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:44:09

**US3052020**

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

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '26 Aug 2020 12:15'	System	26 Aug 2020 16:44:09

US3052020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:44:09

US3052020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:44:09

US3052020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:55:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:44:09



**US3052020**

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

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered empty.	System	26 Aug 2020 16:44:09

US3052020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4) (b) (4)	26 Aug 2020 16:44:14

**US3052020**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	26 Aug 2020 16:44:14

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:06:45', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ed1d7332-1945-469e-ab8b-2fd7e29cdffd'	System	26 Aug 2020 17:03:36
User entered 'Yes (Y)'	System	26 Aug 2020 17:03:36

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:06:49', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ed1d7332-1945-469e-ab8b-2fd7e29cdffd'	System	26 Aug 2020 17:03:36
User entered '98.2'	System	26 Aug 2020 17:03:36

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:06:52', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ed1d7332-1945-469e-ab8b-2fd7e29cdffd'	System	26 Aug 2020 17:03:36
User entered 'No (N)'	System	26 Aug 2020 17:03:36

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:06:55', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ed1d7332-1945-469e-ab8b-2fd7e29cdffd'	System	26 Aug 2020 17:03:36
User entered '26 Aug 2020 13:06'	System	26 Aug 2020 17:03:36



**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '26 Aug 2020 12:50'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:27:25', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '46a6c673-53d0-4c64-b913-a63400c289e6'	System	26 Aug 2020 20:24:24
User entered 'Yes (Y)'	System	26 Aug 2020 20:24:24

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:27:30', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '46a6c673-53d0-4c64-b913-a63400c289e6'	System	26 Aug 2020 20:24:24
User entered '97.3'	System	26 Aug 2020 20:24:24

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:27:35', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '46a6c673-53d0-4c64-b913-a63400c289e6'	System	26 Aug 2020 20:24:24
User entered 'Yes (Y)'	System	26 Aug 2020 20:24:24

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Pt stated taking Tylenol for a headache. Added to conmeds' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 04:15:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:27:38', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '46a6c673-53d0-4c64-b913-a63400c289e6'	Avia McClain-Stocker (b) (4)	23 Mar 2021 21:35:41
User entered '1'	System	26 Aug 2020 20:24:24
	System	26 Aug 2020 20:24:24
	System	26 Aug 2020 20:24:24

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:27:38', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '46a6c673-53d0-4c64-b913-a63400c289e6'	System	26 Aug 2020 20:24:24
User entered '0'	System	26 Aug 2020 20:24:24



US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:27:46', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '46a6c673-53d0-4c64-b913-a63400c289e6'	System	26 Aug 2020 20:24:24
User entered '26 Aug 2020 16:27'	System	26 Aug 2020 20:24:24

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '26 Aug 2020 16:15'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 2'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:43:55', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6d2d3389-f6ee-45dd-892e-bd9d420a7218'	System	28 Aug 2020 00:40:43
User entered 'Yes (Y)'	System	28 Aug 2020 00:40:43

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:01', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6d2d3389-f6ee-45dd-892e-bd9d420a7218'	System	28 Aug 2020 00:40:43
User entered '98.7'	System	28 Aug 2020 00:40:43

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:04', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6d2d3389-f6ee-45dd-892e-bd9d420a7218'	System	28 Aug 2020 00:40:43
User entered 'No (N)'	System	28 Aug 2020 00:40:43

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:06', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6d2d3389-f6ee-45dd-892e-bd9d420a7218'	System	28 Aug 2020 00:40:43
User entered '27 Aug 2020 20:44'	System	28 Aug 2020 00:40:43



**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 3'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:46:51', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a619340e-ee9b-4ca3-8f86-9f295038ac80'	System	29 Aug 2020 11:43:39
User entered 'Yes (Y)'	System	29 Aug 2020 11:43:39

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:46:57', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a619340e-ee9b-4ca3-8f86-9f295038ac80'	System	29 Aug 2020 11:43:39
User entered '98.3'	System	29 Aug 2020 11:43:39

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:46:59', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a619340e-ee9b-4ca3-8f86-9f295038ac80'	System	29 Aug 2020 11:43:39
User entered 'No (N)'	System	29 Aug 2020 11:43:39

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:03', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a619340e-ee9b-4ca3-8f86-9f295038ac80'	System	29 Aug 2020 11:43:39
User entered '29 Aug 2020 07:47'	System	29 Aug 2020 11:43:39

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 4'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:28', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7913bed9-99f5-48d8-b82c-fb35b961c0fd'	System	30 Aug 2020 01:23:12
User entered 'Yes (Y)'	System	30 Aug 2020 01:23:12

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:32', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7913bed9-99f5-48d8-b82c-fb35b961c0fd'	System	30 Aug 2020 01:23:12
User entered '98.7'	System	30 Aug 2020 01:23:12

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:34', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7913bed9-99f5-48d8-b82c-fb35b961c0fd'	System	30 Aug 2020 01:23:12
User entered 'No (N)'	System	30 Aug 2020 01:23:12

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:36', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7913bed9-99f5-48d8-b82c-fb35b961c0fd'	System	30 Aug 2020 01:23:12
User entered '29 Aug 2020 21:26'	System	30 Aug 2020 01:23:12

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 5'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:43:20



**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 6'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:10', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ff90fd6b-4838-4d54-b2ba-c29b493c2554'	System	01 Sep 2020 02:28:50
User entered 'Yes (Y)'	System	01 Sep 2020 02:28:50

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:16', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ff90fd6b-4838-4d54-b2ba-c29b493c2554'	System	01 Sep 2020 02:28:50
User entered '98.8'	System	01 Sep 2020 02:28:50

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:18', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ff90fd6b-4838-4d54-b2ba-c29b493c2554'	System	01 Sep 2020 02:28:50
User entered 'No (N)'	System	01 Sep 2020 02:28:50

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:21', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ff90fd6b-4838-4d54-b2ba-c29b493c2554'	System	01 Sep 2020 02:28:50
User entered '31 Aug 2020 22:32'	System	01 Sep 2020 02:28:50

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 7'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:10', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'eaf91264-2f9f-47b1-89c6-38b93e232e49'	System	01 Sep 2020 20:30:47
User entered 'Yes (Y)'	System	01 Sep 2020 20:30:47

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:14', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'eaf91264-2f9f-47b1-89c6-38b93e232e49'	System	01 Sep 2020 20:30:47
User entered '99.1'	System	01 Sep 2020 20:30:47

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:16', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'eaf91264-2f9f-47b1-89c6-38b93e232e49'	System	01 Sep 2020 20:30:47
User entered 'No (N)'	System	01 Sep 2020 20:30:47

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:18', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'eaf91264-2f9f-47b1-89c6-38b93e232e49'	System	01 Sep 2020 20:30:47
User entered '01 Sep 2020 16:34'	System	01 Sep 2020 20:30:47

US3052020

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8a0e246c-76ca-451a-ad68-12c2d8652118'	System	26 Aug 2020 17:03:46
User entered 'None (1)'	System	26 Aug 2020 17:03:46

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:02', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8a0e246c-76ca-451a-ad68-12c2d8652118'	System	26 Aug 2020 17:03:46
User entered 'No (N)'	System	26 Aug 2020 17:03:46

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:05', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8a0e246c-76ca-451a-ad68-12c2d8652118'	System	26 Aug 2020 17:03:46
User entered 'No (N)'	System	26 Aug 2020 17:03:46

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:07', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8a0e246c-76ca-451a-ad68-12c2d8652118'	System	26 Aug 2020 17:03:46
User entered 'None (1)'	System	26 Aug 2020 17:03:46

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:09', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8a0e246c-76ca-451a-ad68-12c2d8652118'	System	26 Aug 2020 17:03:46
User entered '26 Aug 2020 13:07'	System	26 Aug 2020 17:03:46

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '26 Aug 2020 12:50'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:07', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd4d5a461-6041-4a80-8503-976b81ad0ae7'	System	26 Aug 2020 20:25:16
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 20:25:16

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:19', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd4d5a461-6041-4a80-8503-976b81ad0ae7'	System	26 Aug 2020 20:25:16
User entered 'No (N)'	System	26 Aug 2020 20:25:16

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:29', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd4d5a461-6041-4a80-8503-976b81ad0ae7'	System	26 Aug 2020 20:25:16
User entered 'No (N)'	System	26 Aug 2020 20:25:16

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:36', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd4d5a461-6041-4a80-8503-976b81ad0ae7'	System	26 Aug 2020 20:25:16
User entered 'None (1)'	System	26 Aug 2020 20:25:16

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:39', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd4d5a461-6041-4a80-8503-976b81ad0ae7'	System	26 Aug 2020 20:25:16
User entered '26 Aug 2020 16:28'	System	26 Aug 2020 20:25:16

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '26 Aug 2020 16:15'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 2'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:09', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a9a26a6f-cc22-409d-98cf-4a1ace669769'	System	28 Aug 2020 00:40:56
User entered 'None (1)'	System	28 Aug 2020 00:40:56

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:11', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a9a26a6f-cc22-409d-98cf-4a1ace669769'	System	28 Aug 2020 00:40:56
User entered 'No (N)'	System	28 Aug 2020 00:40:56

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:13', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a9a26a6f-cc22-409d-98cf-4a1ace669769'	System	28 Aug 2020 00:40:56
User entered 'No (N)'	System	28 Aug 2020 00:40:56

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:15', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a9a26a6f-cc22-409d-98cf-4a1ace669769'	System	28 Aug 2020 00:40:56
User entered 'None (1)'	System	28 Aug 2020 00:40:56

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:17', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a9a26a6f-cc22-409d-98cf-4a1ace669769'	System	28 Aug 2020 00:40:56
User entered '27 Aug 2020 20:44'	System	28 Aug 2020 00:40:56

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 3'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:06', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b7d19e5-08ff-4446-8eb6-26e9176c9240'	System	29 Aug 2020 11:43:51
User entered 'None (1)'	System	29 Aug 2020 11:43:51

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:08', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b7d19e5-08ff-4446-8eb6-26e9176c9240'	System	29 Aug 2020 11:43:51
User entered 'No (N)'	System	29 Aug 2020 11:43:51

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:11', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b7d19e5-08ff-4446-8eb6-26e9176c9240'	System	29 Aug 2020 11:43:51
User entered 'No (N)'	System	29 Aug 2020 11:43:51

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:13', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b7d19e5-08ff-4446-8eb6-26e9176c9240'	System	29 Aug 2020 11:43:51
User entered 'None (1)'	System	29 Aug 2020 11:43:51

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:15', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '4b7d19e5-08ff-4446-8eb6-26e9176c9240'	System	29 Aug 2020 11:43:51
User entered '29 Aug 2020 07:47'	System	29 Aug 2020 11:43:51

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 4'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:39', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '169bdbf9-3544-4cf1-9075-e837c7144ee2'	System	30 Aug 2020 01:23:21
User entered 'None (1)'	System	30 Aug 2020 01:23:21

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:40', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '169bdbf9-3544-4cf1-9075-e837c7144ee2'	System	30 Aug 2020 01:23:21
User entered 'No (N)'	System	30 Aug 2020 01:23:21

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:42', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '169bdbf9-3544-4cf1-9075-e837c7144ee2'	System	30 Aug 2020 01:23:21
User entered 'No (N)'	System	30 Aug 2020 01:23:21

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:43', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '169bdbf9-3544-4cf1-9075-e837c7144ee2'	System	30 Aug 2020 01:23:21
User entered 'None (1)'	System	30 Aug 2020 01:23:21

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:44', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '169bdbf9-3544-4cf1-9075-e837c7144ee2'	System	30 Aug 2020 01:23:21
User entered '29 Aug 2020 21:26'	System	30 Aug 2020 01:23:21

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 5'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:43:20



**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 6'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:24', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bc830bb4-8901-42fa-b13e-b10664ba9eaa'	System	01 Sep 2020 02:29:03
User entered 'None (1)'	System	01 Sep 2020 02:29:03

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:27', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bc830bb4-8901-42fa-b13e-b10664ba9eaa'	System	01 Sep 2020 02:29:03
User entered 'No (N)'	System	01 Sep 2020 02:29:03

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:30', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bc830bb4-8901-42fa-b13e-b10664ba9eaa'	System	01 Sep 2020 02:29:03
User entered 'No (N)'	System	01 Sep 2020 02:29:03

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:32', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bc830bb4-8901-42fa-b13e-b10664ba9eaa'	System	01 Sep 2020 02:29:03
User entered 'None (1)'	System	01 Sep 2020 02:29:03

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:34', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'bc830bb4-8901-42fa-b13e-b10664ba9eaa'	System	01 Sep 2020 02:29:03
User entered '31 Aug 2020 22:32'	System	01 Sep 2020 02:29:03

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:43:20



**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:18:45
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 7'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:23', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0d4abb5f-ac95-4305-b9dc-3231f0da51ae'	System	01 Sep 2020 20:31:05
User entered 'None (1)'	System	01 Sep 2020 20:31:05

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:25', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0d4abb5f-ac95-4305-b9dc-3231f0da51ae'	System	01 Sep 2020 20:31:05
User entered 'No (N)'	System	01 Sep 2020 20:31:05

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:31', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0d4abb5f-ac95-4305-b9dc-3231f0da51ae'	System	01 Sep 2020 20:31:05
User entered 'No (N)'	System	01 Sep 2020 20:31:05

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:33', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0d4abb5f-ac95-4305-b9dc-3231f0da51ae'	System	01 Sep 2020 20:31:05
User entered 'None (1)'	System	01 Sep 2020 20:31:05

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:34', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0d4abb5f-ac95-4305-b9dc-3231f0da51ae'	System	01 Sep 2020 20:31:05
User entered '01 Sep 2020 16:34'	System	01 Sep 2020 20:31:05

US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:45
Data hard locked.		25 Feb 2021 15:10:15
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:12', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e7c49d9c-1c7d-4c29-8e6a-305b7895626d'	System	26 Aug 2020 17:04:04
User entered 'None (0)'	System	26 Aug 2020 17:04:04

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:15', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e7c49d9c-1c7d-4c29-8e6a-305b7895626d'	System	26 Aug 2020 17:04:04
User entered 'None (0)'	System	26 Aug 2020 17:04:04

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:16', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e7c49d9c-1c7d-4c29-8e6a-305b7895626d'	System	26 Aug 2020 17:04:04
User entered 'None (0)'	System	26 Aug 2020 17:04:04

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:18', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e7c49d9c-1c7d-4c29-8e6a-305b7895626d'	System	26 Aug 2020 17:04:04
User entered 'None (0)'	System	26 Aug 2020 17:04:04

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:20', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e7c49d9c-1c7d-4c29-8e6a-305b7895626d'	System	26 Aug 2020 17:04:04
User entered 'None (0)'	System	26 Aug 2020 17:04:04

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:21', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e7c49d9c-1c7d-4c29-8e6a-305b7895626d'	System	26 Aug 2020 17:04:04
User entered 'None (0)'	System	26 Aug 2020 17:04:04



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:24', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e7c49d9c-1c7d-4c29-8e6a-305b7895626d'	System	26 Aug 2020 17:04:04
User entered 'No (N)'	System	26 Aug 2020 17:04:04

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T13:07:26', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'e7c49d9c-1c7d-4c29-8e6a-305b7895626d'	System	26 Aug 2020 17:04:04
User entered '26 Aug 2020 13:07'	System	26 Aug 2020 17:04:04

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '26 Aug 2020 12:50'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:46', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0ee9a5bd-4c5d-4d26-8c8b-f17f9b37c884'	System	26 Aug 2020 20:25:41
User entered 'No interference with activity (1)'	System	26 Aug 2020 20:25:41

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:48', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0ee9a5bd-4c5d-4d26-8c8b-f17f9b37c884'	System	26 Aug 2020 20:25:41
User entered 'None (0)'	System	26 Aug 2020 20:25:41

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:53', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0ee9a5bd-4c5d-4d26-8c8b-f17f9b37c884'	System	26 Aug 2020 20:25:41
User entered 'None (0)'	System	26 Aug 2020 20:25:41



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:55', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0ee9a5bd-4c5d-4d26-8c8b-f17f9b37c884'	System	26 Aug 2020 20:25:41
User entered 'None (0)'	System	26 Aug 2020 20:25:41

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:28:58', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0ee9a5bd-4c5d-4d26-8c8b-f17f9b37c884'	System	26 Aug 2020 20:25:41
User entered 'None (0)'	System	26 Aug 2020 20:25:41

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:29:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0ee9a5bd-4c5d-4d26-8c8b-f17f9b37c884'	System	26 Aug 2020 20:25:41
User entered 'None (0)'	System	26 Aug 2020 20:25:41

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:29:02', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0ee9a5bd-4c5d-4d26-8c8b-f17f9b37c884'	System	26 Aug 2020 20:25:41
User entered 'No (N)'	System	26 Aug 2020 20:25:41

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-26T16:29:04', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '0ee9a5bd-4c5d-4d26-8c8b-f17f9b37c884'	System	26 Aug 2020 20:25:41
User entered '26 Aug 2020 16:29'	System	26 Aug 2020 20:25:41

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '26 Aug 2020 16:15'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 2'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:20', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7ab90e15-fbba-44f8-9604-b156fe740cc7'	System	28 Aug 2020 00:41:14
User entered 'None (0)'	System	28 Aug 2020 00:41:14

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:22', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7ab90e15-fbba-44f8-9604-b156fe740cc7'	System	28 Aug 2020 00:41:14
User entered 'None (0)'	System	28 Aug 2020 00:41:14

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:23', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7ab90e15-fbba-44f8-9604-b156fe740cc7'	System	28 Aug 2020 00:41:14
User entered 'None (0)'	System	28 Aug 2020 00:41:14

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:25', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7ab90e15-fbba-44f8-9604-b156fe740cc7'	System	28 Aug 2020 00:41:14
User entered 'None (0)'	System	28 Aug 2020 00:41:14

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:28', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7ab90e15-fbba-44f8-9604-b156fe740cc7'	System	28 Aug 2020 00:41:14
User entered 'None (0)'	System	28 Aug 2020 00:41:14

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:29', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7ab90e15-fbba-44f8-9604-b156fe740cc7'	System	28 Aug 2020 00:41:14
User entered 'None (0)'	System	28 Aug 2020 00:41:14

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:33', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7ab90e15-fbba-44f8-9604-b156fe740cc7'	System	28 Aug 2020 00:41:14
User entered 'No (N)'	System	28 Aug 2020 00:41:14

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-27T20:44:35', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '7ab90e15-fbba-44f8-9604-b156fe740cc7'	System	28 Aug 2020 00:41:14
User entered '27 Aug 2020 20:44'	System	28 Aug 2020 00:41:14



**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 3'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:20', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'af9a87c1-9add-4c21-ba07-75c00a4d133a'	System	29 Aug 2020 11:44:12
User entered 'None (0)'	System	29 Aug 2020 11:44:12

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:22', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'af9a87c1-9add-4c21-ba07-75c00a4d133a'	System	29 Aug 2020 11:44:12
User entered 'None (0)'	System	29 Aug 2020 11:44:12

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:23', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'af9a87c1-9add-4c21-ba07-75c00a4d133a'	System	29 Aug 2020 11:44:12
User entered 'None (0)'	System	29 Aug 2020 11:44:12

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:25', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'af9a87c1-9add-4c21-ba07-75c00a4d133a'	System	29 Aug 2020 11:44:12
User entered 'None (0)'	System	29 Aug 2020 11:44:12

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:27', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'af9a87c1-9add-4c21-ba07-75c00a4d133a'	System	29 Aug 2020 11:44:12
User entered 'None (0)'	System	29 Aug 2020 11:44:12



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:29', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'af9a87c1-9add-4c21-ba07-75c00a4d133a'	System	29 Aug 2020 11:44:12
User entered 'None (0)'	System	29 Aug 2020 11:44:12

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:32', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'af9a87c1-9add-4c21-ba07-75c00a4d133a'	System	29 Aug 2020 11:44:12
User entered 'No (N)'	System	29 Aug 2020 11:44:12

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T07:47:35', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'af9a87c1-9add-4c21-ba07-75c00a4d133a'	System	29 Aug 2020 11:44:12
User entered '29 Aug 2020 07:47'	System	29 Aug 2020 11:44:12

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 4'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:55:49**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:47', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ec829635-72f2-431b-adbb-611d132bf698'	System	30 Aug 2020 01:23:35
User entered 'None (0)'	System	30 Aug 2020 01:23:35

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:19:03
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:49', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ec829635-72f2-431b-adbb-611d132bf698'	System	30 Aug 2020 01:23:35
User entered 'None (0)'	System	30 Aug 2020 01:23:35



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:50', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ec829635-72f2-431b-adbb-611d132bf698'	System	30 Aug 2020 01:23:35
User entered 'None (0)'	System	30 Aug 2020 01:23:35

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:51', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ec829635-72f2-431b-adbb-611d132bf698'	System	30 Aug 2020 01:23:35
User entered 'None (0)'	System	30 Aug 2020 01:23:35

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:53', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ec829635-72f2-431b-adbb-611d132bf698'	System	30 Aug 2020 01:23:35
User entered 'None (0)'	System	30 Aug 2020 01:23:35

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:54', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ec829635-72f2-431b-adbb-611d132bf698'	System	30 Aug 2020 01:23:35
User entered 'None (0)'	System	30 Aug 2020 01:23:35

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:57', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ec829635-72f2-431b-adbb-611d132bf698'	System	30 Aug 2020 01:23:35
User entered 'No (N)'	System	30 Aug 2020 01:23:35

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-29T21:26:58', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'ec829635-72f2-431b-adbb-611d132bf698'	System	30 Aug 2020 01:23:35
User entered '29 Aug 2020 21:26'	System	30 Aug 2020 01:23:35

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:43:20



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 5'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15



**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 6'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:37', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5e7461cd-d147-4110-858f-98fa633f1bb4'	System	01 Sep 2020 02:29:21
User entered 'None (0)'	System	01 Sep 2020 02:29:21

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:39', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5e7461cd-d147-4110-858f-98fa633f1bb4'	System	01 Sep 2020 02:29:21
User entered 'None (0)'	System	01 Sep 2020 02:29:21

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:41', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5e7461cd-d147-4110-858f-98fa633f1bb4'	System	01 Sep 2020 02:29:21
User entered 'None (0)'	System	01 Sep 2020 02:29:21

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:42', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5e7461cd-d147-4110-858f-98fa633f1bb4'	System	01 Sep 2020 02:29:21
User entered 'None (0)'	System	01 Sep 2020 02:29:21



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:44', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5e7461cd-d147-4110-858f-98fa633f1bb4'	System	01 Sep 2020 02:29:21
User entered 'None (0)'	System	01 Sep 2020 02:29:21

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:46', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5e7461cd-d147-4110-858f-98fa633f1bb4'	System	01 Sep 2020 02:29:21
User entered 'None (0)'	System	01 Sep 2020 02:29:21

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:48', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5e7461cd-d147-4110-858f-98fa633f1bb4'	System	01 Sep 2020 02:29:21
User entered 'No (N)'	System	01 Sep 2020 02:29:21

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-08-31T22:32:50', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5e7461cd-d147-4110-858f-98fa633f1bb4'	System	01 Sep 2020 02:29:21
User entered '31 Aug 2020 22:32'	System	01 Sep 2020 02:29:21

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:43:20

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	26 Aug 2020 16:43:20
User entered 'Day 7'	System	26 Aug 2020 16:43:20

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:37', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b74b86d0-ecac-4d5f-9f37-e7fbaeeee855'	System	01 Sep 2020 20:31:19
User entered 'None (0)'	System	01 Sep 2020 20:31:19



US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:19:03
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:39', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b74b86d0-ecac-4d5f-9f37-e7fbaeeee855'	System	01 Sep 2020 20:31:19
User entered 'None (0)'	System	01 Sep 2020 20:31:19

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:40', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b74b86d0-ecac-4d5f-9f37-e7fbaeeee855'	System	01 Sep 2020 20:31:19
User entered 'None (0)'	System	01 Sep 2020 20:31:19

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:42', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b74b86d0-ecac-4d5f-9f37-e7fbaeeee855'	System	01 Sep 2020 20:31:19
User entered 'None (0)'	System	01 Sep 2020 20:31:19

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:19:03
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:43', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b74b86d0-ecac-4d5f-9f37-e7fbaeeee855'	System	01 Sep 2020 20:31:19
User entered 'None (0)'	System	01 Sep 2020 20:31:19

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:45', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b74b86d0-ecac-4d5f-9f37-e7fbaeeee855'	System	01 Sep 2020 20:31:19
User entered 'None (0)'	System	01 Sep 2020 20:31:19

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:47', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b74b86d0-ecac-4d5f-9f37-e7fbaeeee855'	System	01 Sep 2020 20:31:19
User entered 'No (N)'	System	01 Sep 2020 20:31:19

US3052020

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-09-01T16:34:49', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b74b86d0-ecac-4d5f-9f37-e7fbaeeeee855'	System	01 Sep 2020 20:31:19
User entered '01 Sep 2020 16:34'	System	01 Sep 2020 20:31:19

**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:43:20



**US3052020**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:55:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:19:03
Data hard locked.		25 Feb 2021 15:10:15
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:43:20

US3052020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:12:15

US3052020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:12:15

**US3052020**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:12:15

US3052020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:12:15

US3052020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:48:53

**US3052020**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	30 Sep 2020 18:48:53

US3052020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:57:07



US3052020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:57:07

US3052020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:57:07

US3052020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 13:57:07

US3052020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:49:06

US3052020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	30 Sep 2020 18:49:06

US3052020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	08 Oct 2020 13:25:35
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	30 Sep 2020 18:49:26
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	30 Sep 2020 18:49:26

**US3052020**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4)	08 Oct 2020 13:25:35
User entered empty.	Stacey Saldua (b) (4)	30 Sep 2020 18:49:26
	(b) (4)	

US3052020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.	(b) (4)	03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Avia McClain-Stocker	08 Oct 2020 13:25:35
User entered empty.	(b) (4)	
	Stacey Saldua (b) (4)	30 Sep 2020 18:49:26
	(b) (4)	



US3052020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:49:26

US3052020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:50:13

**US3052020**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	30 Sep 2020 18:50:13

US3052020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:54:32

US3052020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:54:32

US3052020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Clinic (Clinic)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 18:54:32

**US3052020**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'VISIT3'	System	30 Sep 2020 18:54:32

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51



US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '10:52'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51

**US3052020**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '30 Sep 2020 10:52'	System	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '98.1' F	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51

**US3052020**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '76'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51

**US3052020**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'bpm'	System	30 Sep 2020 19:01:51



US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '14'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'breaths/min'	System	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '118'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'mmHg'	System	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '79'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'mmHg'	System	30 Sep 2020 19:01:51

US3052020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41

**US3052020**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41



US3052020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:02:13

US3052020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:02:13

US3052020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:02:56

US3052020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '30 Sep 2020'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:02:56

US3052020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '11:25'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:02:56

**US3052020**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
User entered '30 Sep 2020 11:25'	System	30 Sep 2020 19:02:56

US3052020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	30 Sep 2020 19:03:03

US3052020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	30 Sep 2020 19:03:03



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 64'	System	30 Jul 2020 20:16:04

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Have you been exposed to someone with 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '29 Sep 2020 00:01'	System	30 Jul 2020 20:16:04

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '03 Oct 2020 23:59'	System	30 Jul 2020 20:16:04

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 71'	System	30 Jul 2020 20:16:04

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Have you been exposed to someone with 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '06 Oct 2020 00:01'	System	30 Jul 2020 20:16:04

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '10 Oct 2020 23:59'	System	30 Jul 2020 20:16:04



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 78'	System	30 Jul 2020 20:16:04

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-10-13T10:19:33', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '21da55a8-9d3c-4853-98de-f96e984de794'	System	13 Oct 2020 14:15:36
User entered 'No (N)'	System	13 Oct 2020 14:15:36

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

Have you been exposed to someone with 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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-10-13T10:19:36', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '21da55a8-9d3c-4853-98de-f96e984de794'	System	13 Oct 2020 14:15:36
User entered 'No (N)'	System	13 Oct 2020 14:15:36

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-10-13T10:19:38', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '21da55a8-9d3c-4853-98de-f96e984de794'	System	13 Oct 2020 14:15:36
User entered '13 Oct 2020 10:19:38'	System	13 Oct 2020 14:15:36

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '13 Oct 2020 00:01'	System	30 Jul 2020 20:16:04

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '17 Oct 2020 23:59'	System	30 Jul 2020 20:16:04

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 92'	System	30 Jul 2020 20:16:04

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

Have you been exposed to someone with 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

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**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

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**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

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**Generated On: 11 Aug 2021 21:55:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '27 Oct 2020 00:01'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '31 Oct 2020 23:59'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 99'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Have you been exposed to someone with 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '03 Nov 2020 00:01'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '07 Nov 2020 23:59'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 106'	System	30 Jul 2020 20:16:04

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

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)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-11-10T00:10:53', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'db4d9d34-6856-4e39-8fe4-b6defea0bb4c'	System	10 Nov 2020 05:06:19
User entered 'No (N)'	System	10 Nov 2020 05:06:19



US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

Have you been exposed to someone with 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)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:18:11
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-11-10T00:10:58', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'db4d9d34-6856-4e39-8fe4-b6defea0bb4c'	System	10 Nov 2020 05:06:19
User entered 'No (N)'	System	10 Nov 2020 05:06:19

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-11-10T00:11:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'db4d9d34-6856-4e39-8fe4-b6defea0bb4c'	System	10 Nov 2020 05:06:19
User entered '10 Nov 2020 00:11:00'	System	10 Nov 2020 05:06:19

US3052020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.		25 Feb 2021 15:18:11
Data hard locked.		25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '10 Nov 2020 00:01'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 15:18:11
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:10:15
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '14 Nov 2020 23:59'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered 'Day 113'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Have you been exposed to someone with 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Please 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)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '17 Nov 2020 00:01'	System	30 Jul 2020 20:16:04

**US3052020**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:16:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:39:11
Data entry locked.	System	30 Jul 2020 20:16:04
User entered '21 Nov 2020 23:59'	System	30 Jul 2020 20:16:04



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2020-11-21T00:14:31', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '27f0acb4-f8e6-471b-8ec6-8a7eb1b5ad58'	System	21 Nov 2020 05:09:49
User entered 'No (N)'	System	21 Nov 2020 05:09:49

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2020-11-21T00:14:34', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '27f0acb4-f8e6-471b-8ec6-8a7eb1b5ad58'	System	21 Nov 2020 05:09:49
User entered 'No (N)'	System	21 Nov 2020 05:09:49

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-11-21T00:14:37', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '27f0acb4-f8e6-471b-8ec6-8a7eb1b5ad58'	System	21 Nov 2020 05:09:49
User entered '21 Nov 2020 00:14:37'	System	21 Nov 2020 05:09:49

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2020-12-07T12:14:01', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '89317319-187d-4967-ace0-532597880036'	System	07 Dec 2020 17:08:57
User entered 'No (N)'	System	07 Dec 2020 17:08:57

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2020-12-07T12:14:04', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '89317319-187d-4967-ace0-532597880036'	System	07 Dec 2020 17:08:57
User entered 'No (N)'	System	07 Dec 2020 17:08:57

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-12-07T12:14:06', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '89317319-187d-4967-ace0-532597880036'	System	07 Dec 2020 17:08:57
User entered '07 Dec 2020 12:14:06'	System	07 Dec 2020 17:08:57

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2020-12-19T13:43:53', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b3bfe8d7-ecc1-474d-82fc-f8bf10d27c14'	System	19 Dec 2020 18:38:46
User entered 'No (N)'	System	19 Dec 2020 18:38:46

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2020-12-19T13:44:01', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b3bfe8d7-ecc1-474d-82fc-f8bf10d27c14'	System	19 Dec 2020 18:38:46
User entered 'No (N)'	System	19 Dec 2020 18:38:46

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2020-12-19T13:44:03', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'b3bfe8d7-ecc1-474d-82fc-f8bf10d27c14'	System	19 Dec 2020 18:38:46
User entered '19 Dec 2020 13:44:03'	System	19 Dec 2020 18:38:46

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-01-20T17:24:23', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37fdf89b-a9cd-4828-8b77-e5c9b1746144'	System	20 Jan 2021 22:24:56
User entered 'Yes (Y)'	System	20 Jan 2021 22:24:56

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-01-20T17:24:26', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37fdf89b-a9cd-4828-8b77-e5c9b1746144'	System	20 Jan 2021 22:24:56
User entered 'No (N)'	System	20 Jan 2021 22:24:56

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-01-20T17:24:29', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37fdf89b-a9cd-4828-8b77-e5c9b1746144'	System	20 Jan 2021 22:24:56
User entered 'No (N)'	System	20 Jan 2021 22:24:56

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-01-20T17:24:48', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37fdf89b-a9cd-4828-8b77-e5c9b1746144'	System	20 Jan 2021 22:24:56
User entered 'No (N)'	System	20 Jan 2021 22:24:56

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-01-20T17:24:51', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '37fdf89b-a9cd-4828-8b77-e5c9b1746144'	System	20 Jan 2021 22:24:56
User entered '20 Jan 2021 17:24:51'	System	20 Jan 2021 22:24:56

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-01-26T18:00:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8869bfce-6b36-442a-a0d3-6dca6fe89b95'	System	27 Jan 2021 00:38:11
User entered 'No (N)'	System	27 Jan 2021 00:38:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-01-26T18:00:02', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8869bfce-6b36-442a-a0d3-6dca6fe89b95'	System	27 Jan 2021 00:38:11
User entered 'No (N)'	System	27 Jan 2021 00:38:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-01-26T18:00:05', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8869bfce-6b36-442a-a0d3-6dca6fe89b95'	System	27 Jan 2021 00:38:11
User entered '26 Jan 2021 18:00:05'	System	27 Jan 2021 00:38:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-02-06T00:02:42', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '66723121-da99-4cab-ba40-0d87f3a07ca3'	System	06 Feb 2021 05:03:37
User entered 'No (N)'	System	06 Feb 2021 05:03:37

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-02-06T00:02:44', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '66723121-da99-4cab-ba40-0d87f3a07ca3'	System	06 Feb 2021 05:03:37
User entered 'No (N)'	System	06 Feb 2021 05:03:37

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-02-06T00:02:46', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '66723121-da99-4cab-ba40-0d87f3a07ca3'	System	06 Feb 2021 05:03:37
User entered '06 Feb 2021 00:02:46'	System	06 Feb 2021 05:03:37

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-02-13T14:15:46', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5cf5ae20-6cb4-480f-b4cf-3c50d85cbede'	System	13 Feb 2021 19:15:54
User entered 'No (N)'	System	13 Feb 2021 19:15:54

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-02-13T14:15:49', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5cf5ae20-6cb4-480f-b4cf-3c50d85cbede'	System	13 Feb 2021 19:15:54
User entered 'No (N)'	System	13 Feb 2021 19:15:54

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-02-13T14:15:51', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5cf5ae20-6cb4-480f-b4cf-3c50d85cbede' User entered '13 Feb 2021 14:15:51'	System	13 Feb 2021 19:15:54
	System	13 Feb 2021 19:15:54

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-02-20T00:02:17', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd50d0bcc-9e9b-4520-bf22-687182196c2a'	System	20 Feb 2021 05:04:57
User entered 'No (N)'	System	20 Feb 2021 05:04:57



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-02-20T00:02:19', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd50d0bcc-9e9b-4520-bf22-687182196c2a'	System	20 Feb 2021 05:04:57
User entered 'No (N)'	System	20 Feb 2021 05:04:57

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-02-20T00:02:22', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'd50d0bcc-9e9b-4520-bf22-687182196c2a' User entered '20 Feb 2021 00:02:22'	System	20 Feb 2021 05:04:57
	System	20 Feb 2021 05:04:57

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-03-03T19:25:00-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1c407bb0-b908-4914-a8eb-f4fd22ad5c82'	System	04 Mar 2021 00:25:12
User entered 'No (N)'	System	04 Mar 2021 00:25:12

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-03-03T19:25:02-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1c407bb0-b908-4914-a8eb-f4fd22ad5c82'	System	04 Mar 2021 00:25:12
User entered 'No (N)'	System	04 Mar 2021 00:25:12

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-03-03T19:25:04-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '1c407bb0-b908-4914-a8eb-f4fd22ad5c82'	System	04 Mar 2021 00:25:12
User entered '03 Mar 2021 19:25:04'	System	04 Mar 2021 00:25:12



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-03-06T07:07:28-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5dbba30a-2312-471f-9ea5-e08c7eb7f273'	System	06 Mar 2021 12:07:45
User entered 'No (N)'	System	06 Mar 2021 12:07:45

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-03-06T07:07:32-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5dbba30a-2312-471f-9ea5-e08c7eb7f273'	System	06 Mar 2021 12:07:45
User entered 'No (N)'	System	06 Mar 2021 12:07:45

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-03-06T07:07:36-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '5dbba30a-2312-471f-9ea5-e08c7eb7f273'	System	06 Mar 2021 12:07:45
User entered '06 Mar 2021 07:07:36'	System	06 Mar 2021 12:07:45

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-03-13T18:03:43-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a558b67a-7e4b-4429-810d-9c4c1937420e'	System	13 Mar 2021 23:08:13
User entered 'No (N)'	System	13 Mar 2021 23:08:13

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-03-13T18:03:45-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a558b67a-7e4b-4429-810d-9c4c1937420e'	System	13 Mar 2021 23:08:13
User entered 'No (N)'	System	13 Mar 2021 23:08:13

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-03-13T18:03:47-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: 'a558b67a-7e4b-4429-810d-9c4c1937420e'	System	13 Mar 2021 23:08:13
User entered '13 Mar 2021 18:03:47'	System	13 Mar 2021 23:08:13

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-03-20T00:01:17-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '2062c0c1-3e16-46ee-8127-c9a179293f4a'	System	20 Mar 2021 04:02:57
User entered 'No (N)'	System	20 Mar 2021 04:02:57



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-03-20T00:01:23-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '2062c0c1-3e16-46ee-8127-c9a179293f4a'	System	20 Mar 2021 04:02:57
User entered 'No (N)'	System	20 Mar 2021 04:02:57

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-03-20T00:01:26-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '2062c0c1-3e16-46ee-8127-c9a179293f4a' User entered '20 Mar 2021 00:01:26'	System	20 Mar 2021 04:02:57
	System	20 Mar 2021 04:02:57

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-03-27T00:36:26-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8c7a9b8e-7c17-4354-b92e-8ce28c2ce4a6'	System	27 Mar 2021 04:36:38
User entered 'No (N)'	System	27 Mar 2021 04:36:38

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-03-27T00:36:29-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8c7a9b8e-7c17-4354-b92e-8ce28c2ce4a6'	System	27 Mar 2021 04:36:38
User entered 'No (N)'	System	27 Mar 2021 04:36:38

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-03-27T00:36:31-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '8c7a9b8e-7c17-4354-b92e-8ce28c2ce4a6'	System	27 Mar 2021 04:36:38
User entered '27 Mar 2021 00:36:31'	System	27 Mar 2021 04:36:38



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-04-10T07:11:22-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '3238b1b3-f02a-46c6-a86c-61eae1405ad2'	System	10 Apr 2021 11:11:38
User entered 'No (N)'	System	10 Apr 2021 11:11:38

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-04-10T07:11:31-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '3238b1b3-f02a-46c6-a86c-61eae1405ad2'	System	10 Apr 2021 11:11:38
User entered 'No (N)'	System	10 Apr 2021 11:11:38



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-04-10T07:11:35-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '3238b1b3-f02a-46c6-a86c-61eae1405ad2'	System	10 Apr 2021 11:11:38
User entered '10 Apr 2021 07:11:35'	System	10 Apr 2021 11:11:38

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[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 (58d6ade9d96db8ef)', Time: '2021-04-26T19:55:34-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '28b8986d-5dda-4e79-93fa-f72de527f28c'	System	26 Apr 2021 23:55:44
User entered 'No (N)'	System	26 Apr 2021 23:55:44



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

Have you been exposed to someone with 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 (58d6ade9d96db8ef)', Time: '2021-04-26T19:55:36-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '28b8986d-5dda-4e79-93fa-f72de527f28c'	System	26 Apr 2021 23:55:44
User entered 'No (N)'	System	26 Apr 2021 23:55:44

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-04-26T19:55:38-04:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '28b8986d-5dda-4e79-93fa-f72de527f28c'	System	26 Apr 2021 23:55:44
User entered '26 Apr 2021 19:55:38'	System	26 Apr 2021 23:55:44

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:39:11



**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 10:39:11

**US3052020**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:55:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:39:11
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 10:39:11

US3052020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:55:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-03-03T19:24:53-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6845e86b-8d9f-4e33-94f0-a003757cf9a6'	System	04 Mar 2021 00:24:59
User entered 'No (N)'	System	04 Mar 2021 00:24:59

**US3052020**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:16:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58d6ade9d96db8ef)', Time: '2021-03-03T19:24:55-05:00', User OID: 'PatientReportedOutcome (US3052020)', ODM File OID: '6845e86b-8d9f-4e33-94f0-a003757cf9a6'	System	04 Mar 2021 00:24:59
User entered '03 Mar 2021 19:24:55'	System	04 Mar 2021 00:24:59

US3052020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:54:15



US3052020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '20 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:54:15

US3052020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:54:15

US3052020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:54:15

US3052020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	20 Oct 2020 20:54:19

**US3052020**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:23:13
Data entry locked.		03 Apr 2021 20:52:41
User entered 'I'	System	20 Oct 2020 20:54:19

**US3052020**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:28:12

**US3052020**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:28:12

**US3052020**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:28:12



**US3052020**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 13:28:12

US3052020

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	11 Dec 2020 20:48:54

**US3052020**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered 'I'	System	11 Dec 2020 20:48:54

**US3052020**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	amy sheets (b) (4)	31 Dec 2020 20:00:35

US3052020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered '27 Dec 2020'	amy sheets (b) (4)	31 Dec 2020 20:00:35

**US3052020**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Contact Made (CONTACT MADE)'	amy sheets (b) (4)	31 Dec 2020 20:00:35

US3052020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	31 Dec 2020 20:00:35

US3052020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'Yes (Y)'	amy sheets (b) (4)	31 Dec 2020 20:00:40



**US3052020**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered 'I'	System	31 Dec 2020 20:00:40

**US3052020**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:59:01

US3052020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:55:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:46:38
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 07:44:38
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data correct' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 13:59:14
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Mar 2021 13:59:01
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Mar 2021 13:59:01

**US3052020**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:46:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:59:01

**US3052020**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:46:38
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:59:01

US3052020

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 14:46:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:59:22

**US3052020**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered 'I'	System	12 Mar 2021 13:59:22

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:17



**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:17

US3052020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:17

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered 'VISIT4'	System	31 Mar 2021 18:26:17

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24

US3052020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered empty.	System	31 Mar 2021 18:26:24

US3052020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24



US3052020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered empty.	System	31 Mar 2021 18:26:24

US3052020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered empty.	System	31 Mar 2021 18:26:24

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered empty.	System	31 Mar 2021 18:26:24



US3052020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:24

US3052020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:55:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered empty.	System	31 Mar 2021 18:26:24

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:55:49**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22

US3052020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:58

US3052020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:55:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:26:58

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:55:49**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:27:03

US3052020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:27:03



**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:55:49**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:57
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:27:03

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:55:49**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered empty.	System	31 Mar 2021 18:27:03

US3052020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:42:32

**US3052020**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:57:22
User entered 'I'	System	26 Mar 2021 20:42:32

**US3052020**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:26:34
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:42:48

**US3052020**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:26:34
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:34
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:42:48

**US3052020**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:26:34
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:42:48

**US3052020**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:26:34
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:34
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:42:48



**US3052020**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:26:34
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:43:08

**US3052020**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:26:34
User entered 'I'	System	26 Mar 2021 20:43:08

**US3052020**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:35:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:20

**US3052020**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:35:02
User entered '26 Apr 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:20

**US3052020**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:35:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:20

**US3052020**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:55:49**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:35:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 20:08:20

US3052020

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:35:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:08:25

**US3052020**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:55:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 20:08:25



US3052020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 18:30:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 18:30:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 18:30:20
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 18:30:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 18:30:12
User entered 'No (N)'		31 Mar 2021 18:29:07

**US3052020**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:34
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 18:29:07

US3052020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:55:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 13:23:34
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:29:07

**US3052020**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:55:49**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 18:30:20
User entered empty.	System	31 Mar 2021 18:30:12
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 18:29:07

**US3052020**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:55:49**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:06:33

**US3052020**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:55:49**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:06:33

US3052020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:12:28

US3052020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:55:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:30
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 18:12:28



**US3052020**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:55:49**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:12:28

**US3052020**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:55:49**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:12:28

US3052020

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:12:34

**US3052020**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:55:49**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:12:34

**US3052020**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:55:49**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:18:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:12:34

**US3052020**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:55:49**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:12:34

**US3052020**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 21:55:49**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	28 Oct 2020 18:01:44

Were any prior/concomitant medications and/or vaccinations taken?

FDA-CBER-2022-1614-0215293



US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:55:49

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'NO' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 17:57:24
User entered 'No (N)' reason for change: Data Entry Error		08 Mar 2021 17:57:17
User opened query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.'		05 Feb 2021 09:19:53
(Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	Avia McClain-Stocker	09 Nov 2020 14:03:48
	(b) (4)	
User entered 'No (N)'	Avia McClain-Stocker	28 Oct 2020 18:03:18
	(b) (4)	

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Nov 2020 14:05:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 14:05:33
Data point term sent to Coder	System	09 Nov 2020 14:04:49
User entered 'Venlafaxine'	Avia McClain-Stocker (b) (4)	09 Nov 2020 14:04:43

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered 'No (N)'	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
User closed query 'Per CDM, re-query: Response noted; however, ANXIETY is not present on the Medical History page. Please update to record a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 15:00:16
Query 'Per CDM, re-query: Response noted; however, ANXIETY is not present on the Medical History page. Please update to record a medical condition and all applicable details to the appropriate eCRF.' answered with 'done' (Site from DM).		17 Mar 2021 15:51:20
User opened query 'Per CDM, re-query: Response noted; however, ANXIETY is not present on the Medical History page. Please update to record a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).		17 Mar 2021 06:47:15
User closed query 'Per CDM: Response noted; however no update made on AE page. Kindly review and update accordingly. Otherwise clarify. Thank you.' (Site from DM).		17 Mar 2021 06:47:15
Query 'Per CDM: Response noted; however no update made on AE page. Kindly review and update accordingly. Otherwise clarify. Thank you.' answered with 'this is not an AE, ongoing medical condition' (Site from DM).		16 Mar 2021 13:07:16
User opened query 'Per CDM: Response noted; however no update made on AE page. Kindly review and update accordingly. Otherwise clarify. Thank you.' (Site from DM).		11 Mar 2021 19:38:00
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).		11 Mar 2021 19:36:36
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'ANXIETY' (Site from DM).		08 Mar 2021 17:30:51

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EAB) (1725)

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US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:49

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:44:23
User entered 'Anxiety'	Avia McClain-Stocker (b) (4)	09 Nov 2020 14:04:43

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered '37.5'	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered 'mg (mg)'	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered empty.	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	



**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered 'twice daily (BID)'	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered empty.	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
User entered 'Oral (ORAL)'	(b) (4) Avia McClain-Stocker (b) (4)	09 Nov 2020 14:04:43

US3052020

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered empty.	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered '26 Aug 2020'	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered '0'	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered 'Yes (Y)'	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:55:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered empty.	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	



**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:34:35
	(b) (4)	
User entered 'No (N)'	Avia McClain-Stocker	09 Nov 2020 14:04:43
	(b) (4)	

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Nov 2020 14:04:43

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 14:04:43

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:55:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 14:04:43

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 21:56:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 21:56:41
Data point term sent to Coder	System	23 Mar 2021 21:41:56
Data point term sent to Coder	System	23 Mar 2021 21:40:55
User entered 'Tylenol'	Avia McClain-Stocker (b) (4)	23 Mar 2021 21:40:53

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	23 Mar 2021 21:40:53

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered 'Headache after 2nd injection'	(b) (4) Avia McClain-Stocker (b) (4)	23 Mar 2021 21:40:53

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered '325'	(b) (4) Avia McClain-Stocker	23 Mar 2021 21:40:53
	(b) (4)	



US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered 'mg (mg)'	(b) (4) Avia McClain-Stocker (b) (4)	23 Mar 2021 21:40:53

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered empty.	(b) (4) Avia McClain-Stocker	23 Mar 2021 21:40:53
	(b) (4)	

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered 'once (ONCE)'	(b) (4) Avia McClain-Stocker	23 Mar 2021 21:40:53
	(b) (4)	

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered empty.	(b) (4) Avia McClain-Stocker	23 Mar 2021 21:40:53
	(b) (4)	

US3052020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:55:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Mar 2021 21:41:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 21:41:05
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	23 Mar 2021 21:41:05
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 21:40:53
User entered empty.	Avia McClain-Stocker (b) (4)	23 Mar 2021 21:40:53

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered empty.	(b) (4) Avia McClain-Stocker	23 Mar 2021 21:40:53
	(b) (4)	

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

**Start date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered '26 Aug 2020'	(b) (4) Avia McClain-Stocker (b) (4)	23 Mar 2021 21:40:53

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered '0'	(b) (4) Avia McClain-Stocker (b) (4)	23 Mar 2021 21:40:53



**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	23 Mar 2021 21:40:53

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered '26 Aug 2020'	(b) (4) Avia McClain-Stocker	23 Mar 2021 21:40:53
	(b) (4)	

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User signature succeeded.	Yaa Oppong (b) (4)	26 Mar 2021 20:19:01
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	23 Mar 2021 21:40:53

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User entered empty.	System	23 Mar 2021 21:40:53

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User entered empty.	System	23 Mar 2021 21:40:53

**US3052020**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:55:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:01
User entered empty.	System	23 Mar 2021 21:40:53

US3052020

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 21:55:49**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Borger (b) (4)	23 Feb 2021 07:46:38
	(b) (4)	
User entered 'No (N)'	Avia McClain-Stocker	28 Oct 2020 18:01:50
	(b) (4)	