

US3202025 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:39:33

All time stamps listed in this document are displayed in GMT

US3202025

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

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[Participant ID](#)

US3202025

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

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US3202025

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3202025

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	72
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Date of Informed Consent ( <i>dd MMM yyyy</i> )	6 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:43:53

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

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

US3202025

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Condition	VACETOMY
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Condition	CARDIAC STENT PLACED
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Condition	HYPERLIPIDEMA
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	06 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:40 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 09:40
Height ( <i>xxx.x</i> )	170.8 cm
Weight ( <i>xxx.x</i> )	98.7 kg
BMI ( <i>xxx.x</i> )	33.83307 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:43:53

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:43:53

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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) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	06 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 184808

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

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)	6 AUG 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 09:40
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	6 AUG 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 11:15
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

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.*

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

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) 6 AUG 2020

What was the treatment time? (00:00-23:59) 10:26 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 10:26

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 AUG 2020
Collection time (00:00-23:59)	10:00 (24 HR)
Collection date and time (derived)	06 AUG 2020 10:00

US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:57	06 AUG 2020 09:57
Nasopharyngeal Swab 2	No		

US3202025

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.2 °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 06 AUG 2020 11:10

PC Open Date & Time 06 AUG 2020 10:46

PC Close Date & Time 06 AUG 2020 13:16

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**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 98.0 °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	06 AUG 2020 18:51
PC Open Date & Time	06 AUG 2020 14:11
PC Close Date & Time	07 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**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

07 AUG 2020 18:24

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 18:02

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

09 AUG 2020 18:12

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 17:00

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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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

97.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

11 AUG 2020 17:47

---

PC Open Date & Time

11 AUG 2020 12:00

---

PC Close Date & Time

12 AUG 2020 11:59

---

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 19:13

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**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

06 AUG 2020 11:11

PC Open Date & Time

06 AUG 2020 10:46

PC Close Date & Time

06 AUG 2020 13:16

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**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

06 AUG 2020 18:48

PC Open Date & Time

06 AUG 2020 14:11

PC Close Date & Time

07 AUG 2020 11:59



US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**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

07 AUG 2020 18:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**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

08 AUG 2020 18:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**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

09 AUG 2020 18:13

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 17:01

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 17:52

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 19:14

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**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 ☐

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 11:12
PC Open Date & Time	06 AUG 2020 10:46
PC Close Date & Time	06 AUG 2020 13:16



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**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 ☐

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 18:47
PC Open Date & Time	06 AUG 2020 14:11
PC Close Date & Time	07 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:27
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**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 ☒

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 18:04
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**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 ☒

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:12
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**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 ☒

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 17:02
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 17:52
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**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

60 of 1858

EAB) (1725)

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 19:15
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3202025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3202025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:43:52

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:43:52

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:43:52

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:43:52

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

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)	03 SEP 2020
Time of assessment (00:00-23:59)	11:34 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 11:34
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:00
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3202025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

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.*



US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

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) 3 SEP 2020

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

Treatment Date and Time (derived) 3 SEP 2020 12:19

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

What was the frequency of the study treatment dosing? ONCE

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

US3202025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	11:50 (24 HR)
Collection date and time (derived)	3 SEP 2020 11:50

US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:46	3 SEP 2020 11:46
Nasopharyngeal Swab 2	No		

US3202025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 13:07

PC Open Date & Time

03 SEP 2020 12:39

PC Close Date & Time

03 SEP 2020 15:09

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 16:40

PC Open Date & Time

03 SEP 2020 16:04

PC Close Date & Time

04 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**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

99.0 °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

04 SEP 2020 17:55

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:17

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**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

98.0 °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

06 SEP 2020 16:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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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

98.0 °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

07 SEP 2020 16:48

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**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

99.2 °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

08 SEP 2020 15:32

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**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

99.2 °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

09 SEP 2020 21:30

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**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

03 SEP 2020 13:07

PC Open Date & Time

03 SEP 2020 12:39

PC Close Date & Time

03 SEP 2020 15:09

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**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

03 SEP 2020 16:40

PC Open Date & Time

03 SEP 2020 16:04

PC Close Date & Time

04 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**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

04 SEP 2020 17:56

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**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

05 SEP 2020 19:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**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

06 SEP 2020 16:02

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**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

07 SEP 2020 16:49

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**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

08 SEP 2020 15:32

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**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

09 SEP 2020 21:30

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**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 ☐

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 13:08
PC Open Date & Time	03 SEP 2020 12:39
PC Close Date & Time	03 SEP 2020 15:09

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**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 ☐

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 16:41
PC Open Date & Time	03 SEP 2020 16:04
PC Close Date & Time	04 SEP 2020 11:59



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**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 ☒

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 17:57
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**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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US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**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 ☒

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 16:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**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 ☒

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 16:50
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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 ☒

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 15:33
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**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 ☒

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 21:31
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp

10 SEP 2020 13:32

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3202025

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:39:33

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 13:33
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3202025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3202025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:43:53

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	09:26 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 09:26
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

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.*

US3202025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	09:35 (24 HR)
Collection date and time (derived)	1 OCT 2020 09:35



US3202025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:44:33

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 OCT 2020 12:25:54

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 16:22:45

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 20:28:49

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 17:17:23

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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="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	13 NOV 2020 14:27:19
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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 <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"/>

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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



US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 14:28:01

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 11:24:51

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 13:23:54

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2020 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 08:32:42

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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

30 DEC 2020 19:37:50

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 152

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

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

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

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



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 22:18:26
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 10:19:03

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 17:06:36

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 FEB 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 11:34:52

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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13 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

---

[Patient Cloud Close Date & Time](#)

---

24 FEB 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 11:34:36

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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

09 MAR 2021 10:41:08

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 18:51:40

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

<b>TIMEPOINT</b>	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 10:11:05
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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

07 APR 2021 12:01:59

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 21:37:55

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 08:07:21

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 APR 2021 10:47:55
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 MAY 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	19 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 JUN 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	03 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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 <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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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14 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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 <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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59
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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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 <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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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="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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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 <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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 FEB 2022 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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="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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 APR 2022 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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 <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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2022 23:59

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 712

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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23 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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="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"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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="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"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 AUG 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59
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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**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 ☐

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3202025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:39:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 11:33:59

US3202025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:36:28

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:36:28

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3202025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 JAN 2021

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

Comments LEFT A VOICE MESSAGE

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202025

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	3 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

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) \_\_\_\_\_



US3202025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

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.*

US3202025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00-23:59)	09:12 (24 HR)
Collection date and time (derived)	3 MAR 2021 09:12

US3202025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

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*

**US3202025**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:33**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202025

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:39:33

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>

**US3202025**

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

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

**Generated On: 09 Jun 2021 15:39:33**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3202025

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3202025

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 17:52:23

Generated On: 09 Jun 2021 15:39:33

Date of updated informed consent (dd MMM yyyy) 22 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 22 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3202025

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

09:53 (24 HR)

Collection date and time (derived)

22 JAN 2021 09:53

US3202025

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	22 JAN 2021
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Collection time (00:00 - 23:59)	09:51
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Collection Date and Time (derived)	22 JAN 2021 09:51
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US3202025

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 May 2021 19:42:41

Generated On: 09 Jun 2021 15:39:33

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Did the participant experience any adverse events?

Yes ☒

No ☐

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If Yes, enter details on the Adverse Events form.

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US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 19:42:41

Generated On: 09 Jun 2021 15:39:33

AEID	USA-US128-2021-MRNA-1273-P30 1000021
Adverse event	WORSENING OF BACK PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 19:42:41

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input checked="" type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 19:42:41

Generated On: 09 Jun 2021 15:39:33

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SUBJ LEFT VM YESTERDAY  
STATING HE WAS GOING TO  
HOSPITAL B/C OF BACK PAIN.  
WHEN CONTACTED THIS AM,  
STATED WAS BEING PREPPED  
FOR BACK SURGERY AT TIME  
OF CALL. NO OTHER DETAILS  
ARE KNOWN AT THIS TIME AS  
THIS WAS NOT A GOOD TIME  
FOR SUBJ TO ANSWER LOT OF  
QUESTIONS. RECORDS HAVE  
BEEN REQUESTED.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 13:16:47

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

Yes ☒

No ☐

---

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

---



US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Name of Medication LISINOPRIL/HCTZ

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:16:47

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Name of Medication SERTRALINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Name of Medication JANUVIA

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2014
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

Name of Medication HYDROCO/ACETAMINO

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 13:16:47

Generated On: 09 Jun 2021 15:39:33

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:39:33

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3202025

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:39:33

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 19:42:41

Generated On: 09 Jun 2021 15:39:33

SAEID	USA-US128-2021-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 19:42:41

Generated On: 09 Jun 2021 15:39:33

SAEID	USA-US128-2021-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	29/APR/2021 14:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3202025 (Prod: WR-ClinSearch, LLC)

**US3202025**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:39:33**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:30:48
User entered 'US3202025'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:19:35

US3202025

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	06 Aug 2020 13:44:52



US3202025

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:19:36

US3202025

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[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 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	06 Aug 2020 13:44:52

**US3202025**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User entered 'SCRN'	System	06 Aug 2020 13:44:52

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:19:37

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '71'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'YEARS'	System	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '72'	System	06 Aug 2020 13:45:10

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Male (M)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:16:02



US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'I'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 15:16:02



US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:33

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 15:16:02

US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:08:27
User entered '6 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 13:45:10

US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Aug 2020'	System	06 Aug 2020 13:45:10

US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2020'	System	06 Aug 2020 13:45:10

US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:08:27
User entered 'Amendment 1 (1)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 13:45:10

US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:08:27
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 13:45:10

US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:08:27
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 13:45:10



US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:08:27
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 13:45:10

US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:08:27
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	06 Aug 2020 13:45:10

US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:08:27
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:19:36

US3202025

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'I'	System	06 Aug 2020 13:45:17

US3202025

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:39:33

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	06 Aug 2020 13:45:17

US3202025

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:39:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:18:23

US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 15:20:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 15:20:12
Data point term sent to Coder	System	22 Aug 2020 15:18:52
User entered 'Seasonal allergies'	zackery harmon (b) (4)	22 Aug 2020 15:18:43

US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 2005'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:18:43



US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:18:43

US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:18:43

US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:18:43

US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:18:43

US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 2005'	System	22 Aug 2020 15:18:43

US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2005'	System	22 Aug 2020 15:18:43

US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	22 Aug 2020 15:18:43

US3202025

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	22 Aug 2020 15:18:43



US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 15:20:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 15:20:12
Data point term sent to Coder	System	22 Aug 2020 15:19:52
User entered 'Type 2 diabetes'	zackery harmon (b) (4)	22 Aug 2020 15:18:59

US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 2011'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:18:59

US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:18:59

US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:18:59

US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:18:59

US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:18:59

US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 2011'	System	22 Aug 2020 15:18:59

US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2011'	System	22 Aug 2020 15:18:59



US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	22 Aug 2020 15:18:59

US3202025

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	22 Aug 2020 15:18:59

US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 03:33:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 03:33:11
Data point term sent to Coder	System	16 Sep 2020 03:32:23
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 03:31:57
User entered 'HYPERTENSION' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:31:57
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 15:20:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 15:20:12
Data point term sent to Coder	System	22 Aug 2020 15:19:52
User entered 'HTN'	zackery harmon (b) (4)	22 Aug 2020 15:19:20

US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 2011'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:19:20

US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:19:20

US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:19:20

US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:19:20

US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:19:20



US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 2011'	System	22 Aug 2020 15:19:20

US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2011'	System	22 Aug 2020 15:19:20

US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	22 Aug 2020 15:19:20

US3202025

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	22 Aug 2020 15:19:20

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User closed query 'Per DM CLR: Please specify the location and/or type of CHRONIC PAIN (e.g. Chronic Back Pain). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 03:26:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 03:26:57
Query 'Per DM CLR: Please specify the location and/or type of CHRONIC PAIN (e.g. Chronic Back Pain). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'done' (Site from DM).	Erica Osmundsen (b) (4)	16 Sep 2020 03:26:24
Data point term sent to Coder	System	16 Sep 2020 03:26:21
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 03:26:07
User entered 'chronic back pain' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:26:07
User opened query 'Per DM CLR: Please specify the location and/or type of CHRONIC PAIN (e.g. Chronic Back Pain). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:08:13

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

Condition

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Chronic pain - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 15:22:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 15:22:13
Data point term sent to Coder	System	22 Aug 2020 15:21:53
User entered 'Chronic pain'	zackery harmon (b) (4)	22 Aug 2020 15:21:33
	(b) (4)	

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 2010'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:21:33

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:21:33



US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:21:33

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:21:33

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:21:33

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 2010'	System	22 Aug 2020 15:21:33

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2010'	System	22 Aug 2020 15:21:33

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	22 Aug 2020 15:21:33

US3202025

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:39:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	22 Aug 2020 15:21:33

US3202025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 07:17:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 07:17:40
Data point term sent to Coder	System	22 Aug 2020 15:22:55
User entered 'Vacetomy'	zackery harmon (b) (4)	22 Aug 2020 15:22:03



US3202025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 1972'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:22:03

US3202025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:22:03

US3202025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	22 Aug 2020 15:22:22
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	22 Aug 2020 15:22:03
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:22:03

US3202025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 1972' reason for change:	(b) (4)	
Data Entry Error	zackery harmon (b) (4)	22 Aug 2020 15:22:22
User entered empty.	(b) (4)	
	zackery harmon (b) (4)	22 Aug 2020 15:22:03
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:22:03

US3202025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 1972'	System	22 Aug 2020 15:22:03

US3202025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '1972'	System	22 Aug 2020 15:22:03

US3202025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 1972'	System	22 Aug 2020 15:22:22
User entered empty.	System	22 Aug 2020 15:22:03



US3202025

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '1972'	System	22 Aug 2020 15:22:22
User entered empty.	System	22 Aug 2020 15:22:03

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:04:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 03:24:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 03:24:55
Data point term sent to Coder	System	16 Sep 2020 03:23:19
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'done' (Site from DM).	Erica Osmundsen (b) (4)	16 Sep 2020 03:22:46
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 03:22:30
User entered 'cardiac STENT placed' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:22:30
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:09:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 07:23:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 07:23:43
Data point term sent to Coder	System	22 Aug 2020 15:24:58

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

[Condition](#)

Audit	User	Time (GMT)
User entered 'stent'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:24:01

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 2008'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:24:01

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:24:01

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:24:01
	(b) (4)	

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 2008'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:24:01

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:24:01



US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 2008'	System	22 Aug 2020 15:24:01

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2008'	System	22 Aug 2020 15:24:01

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 2008'	System	22 Aug 2020 15:24:01

US3202025

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2008'	System	22 Aug 2020 15:24:01

US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 03:32:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 03:32:56
Data point term sent to Coder	System	16 Sep 2020 03:32:23
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 03:32:21
User entered 'HYPERLIPIDEMA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:32:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 14:52:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Sep 2020 14:52:44
Data point term sent to Coder	System	13 Sep 2020 14:52:16
User entered 'hyperlipidema'	zackery harmon (b) (4)	13 Sep 2020 14:51:59

US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 2011'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 14:51:59

US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 14:51:59

US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 14:51:59



US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Sep 2020 14:51:59

US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 14:51:59

US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 2011'	System	13 Sep 2020 14:51:59

US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2011'	System	13 Sep 2020 14:51:59

US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	13 Sep 2020 14:51:59

US3202025

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	13 Sep 2020 14:51:59

US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
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)	13 Sep 2020 14:58:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 14:58:00
Data point term sent to Coder	System	13 Sep 2020 14:57:19
User entered 'anxiety'	zackery harmon (b) (4)	13 Sep 2020 14:56:44
	(b) (4)	

US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'UN UNK 2015' reason for change:	(b) (4)	
Data Entry Error	zackery harmon (b) (4)	13 Sep 2020 14:56:55
User entered 'un UNK 2011'	(b) (4)	
	zackery harmon (b) (4)	13 Sep 2020 14:56:44
	(b) (4)	



US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Sep 2020 14:56:44

US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 14:56:44

US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Sep 2020 14:56:44

US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 14:56:44

US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 2015'	System	13 Sep 2020 14:56:55
User entered 'Jan 2011'	System	13 Sep 2020 14:56:44

US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2015'	System	13 Sep 2020 14:56:55
User entered '2011'	System	13 Sep 2020 14:56:44

US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	13 Sep 2020 14:56:44

US3202025

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	13 Sep 2020 14:56:44



US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 03:25:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 03:25:57
Data point term sent to Coder	System	16 Sep 2020 03:25:20
User entered 'coronary artery disease'	Erica Osmundsen (b) (4)	16 Sep 2020 03:24:34

US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'un UNK 2008'	Erica Osmundsen (b) (4)	16 Sep 2020 03:24:34

US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	16 Sep 2020 03:24:34

US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	16 Sep 2020 03:24:34

US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Sep 2020 03:24:34

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US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	16 Sep 2020 03:24:34

US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered 'Jan 2008'	System	16 Sep 2020 03:24:34

US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered '2008'	System	16 Sep 2020 03:24:34



US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	16 Sep 2020 03:24:34

US3202025

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User entered empty.	System	16 Sep 2020 03:24:34

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '06 Aug 2020'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05
	(b) (4)	

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '09:40'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User entered '06 Aug 2020 09:40'	System	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '170.8' cm	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05
DataPoint set to visible.	(b) (4) System	06 Aug 2020 13:45:17

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '98.7' kg	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05
DataPoint set to visible.	(b) (4) System	06 Aug 2020 13:45:17



US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
Amendment Manager: User entered '33.83307'	System	16 Sep 2020 23:45:04
User entered '33.8'	System	22 Aug 2020 15:39:05
DataPoint set to visible.	System	06 Aug 2020 13:45:17

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User entered 'kg/m2'	System	22 Aug 2020 15:39:05
DataPoint set to visible.	System	06 Aug 2020 13:45:17

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05
	(b) (4)	

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05
	(b) (4)	

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05
	(b) (4)	

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User entered 'bpm'	System	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05



US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User entered 'breaths/min'	System	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User entered 'mmHg'	System	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26
User entered 'mmHg'	System	22 Aug 2020 15:39:05

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26

US3202025

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:26

US3202025

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	zackery harmon (b) (4)	29 Aug 2020 15:04:06
User entered 'No (N)'	(b) (4)	
	zackery harmon (b) (4)	22 Aug 2020 15:36:32
	(b) (4)	



US3202025

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 10:09:11
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 16:41:57
User entered '06 Aug 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Aug 2020 15:04:06
User entered empty.	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:36:32

US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

[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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

**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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

**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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

**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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

[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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

[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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

**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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:38:01



US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

**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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

[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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

**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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

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**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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:38:01
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:38:01
	(b) (4)	

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:38:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01



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Folder: Screening

Form: Risk of Exposure

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**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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

[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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:38:01

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Folder: Screening

Form: Risk of Exposure

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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 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	zackery harmon (b) (4)	22 Aug 2020 15:38:01

US3202025

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'I'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:38:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '0'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:38:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:20
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:38:01

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:27

US3202025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '06 Aug 2020'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:27
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Clinic (Clinic)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:39:27

US3202025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'VISIT1'	System	22 Aug 2020 15:39:27

US3202025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:44:53

US3202025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:33

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:26:55
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:26:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 13:44:53
User entered '184808' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:44:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:44:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:33

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:39:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:33

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:55

US3202025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:33

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Aug 2020 15:40:01
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4)	22 Aug 2020 15:40:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	22 Aug 2020 15:39:55
	zackery harmon (b) (4)	22 Aug 2020 15:39:55
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:33

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:55

US3202025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:39:55
	(b) (4)	

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:20:53
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered by data change (Site from DM).	System	12 Sep 2020 18:53:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:53:43
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:31:42
User entered '170.8' cm	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:20:56
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered by data change (Site from DM).	System	12 Sep 2020 18:53:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:53:43
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:31:46
User entered '98.7' kg	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:20:53
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered by data change (Site from DM).	System	12 Sep 2020 18:53:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:53:43
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:31:42
User entered '170.8' cm	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:20:56
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered by data change (Site from DM).	System	12 Sep 2020 18:53:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:53:43
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:31:46
User entered '98.7' kg	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:42:55
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '6 Aug 2020'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '09:40'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '6 Aug 2020 09:40'	System	22 Aug 2020 15:42:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '37.0' C	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:42:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:42:55
	(b) (4)	

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '72'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'bpm'	System	22 Aug 2020 15:42:55



US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '16'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'breaths/min'	System	22 Aug 2020 15:42:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '116'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'mmHg'	System	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '80'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:42:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'mmHg'	System	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:20:53
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered by data change (Site from DM).	System	12 Sep 2020 18:53:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:53:43
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:31:42
User entered '170.8' cm	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 08:20:56
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered by data change (Site from DM).	System	12 Sep 2020 18:53:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:53:43
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:31:46
User entered '98.7' kg	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55



US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '6 Aug 2020'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '11:15'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '6 Aug 2020 11:15'	System	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Aug 2020 15:43:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Aug 2020 15:43:13
User entered '36.2' C reason for change: Data Entry Error	zackery harmon (b) (4)	22 Aug 2020 15:43:13
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Aug 2020 15:42:55
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:42:55
	(b) (4)	

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Aug 2020 15:43:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Aug 2020 15:43:26
User entered 'Oral (Oral)' reason for change: Data Entry Error	zackery harmon (b) (4)	22 Aug 2020 15:43:26
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Aug 2020 15:43:13
User entered empty.	System	22 Aug 2020 15:42:55
	zackery harmon (b) (4)	
	(b) (4)	

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:42:55
	(b) (4)	



US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '83'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'bpm'	System	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 13:29:28
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:29:26
Query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' answered with 'Field corrected' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 16:52:37
User entered '16' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 16:52:17
User opened query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:27:24
Amendment Manager: Query text changed to "Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:45:03
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Ok per sub I for subject to depart site' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 18:55:48
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Aug 2020 15:42:55
User entered '26'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'breaths/min'	System	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '142'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'mmHg'	System	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '68'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:42:55

US3202025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'mmHg'	System	22 Aug 2020 15:42:55



US3202025

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	zackery harmon (b) (4)	29 Aug 2020 15:03:52
User entered 'Yes (Y)'	(b) (4)	
	zackery harmon (b) (4)	22 Aug 2020 15:40:25
	(b) (4)	

US3202025

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty; reason for change Data Entry Error	(b) (4)	
	zackery harmon (b) (4)	29 Aug 2020 15:03:52
User entered '06 Aug 2020'	(b) (4)	
	zackery harmon (b) (4)	22 Aug 2020 15:40:25
	(b) (4)	

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	06 Aug 2020 14:32:43

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	06 Aug 2020 14:32:43

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	06 Aug 2020 14:32:43

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 14:32:43

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '6 Aug 2020'	(b) (4) Erica Osmundsen (b) (4)	06 Aug 2020 14:32:43

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '10:26'	(b) (4) Erica Osmundsen (b) (4)	06 Aug 2020 14:32:43



US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '6 Aug 2020 10:26'	System	06 Aug 2020 14:32:43

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) Erica Osmundsen (b) (4)	06 Aug 2020 14:32:43

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'ONCE'	System	06 Aug 2020 14:32:43

US3202025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 14:32:43

US3202025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:40:48

US3202025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '06 Aug 2020'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:40:48
	(b) (4)	

US3202025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '10:00'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:40:48

US3202025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '06 Aug 2020 10:00'	System	22 Aug 2020 15:40:48



US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:39:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '06 Aug 2020'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:41:03
	(b) (4)	

US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:41:03

US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:41:03

US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '09:57'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:41:03

US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '06 Aug 2020 09:57'	System	22 Aug 2020 15:41:03

US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:41:03

US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:41:03

US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:41:03



US3202025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered empty.	System	22 Aug 2020 15:41:03

US3202025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:12:14

US3202025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'I'	System	21 Aug 2020 21:12:14

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:10:09', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '899ddd40-9b1c-4cc7-846c-ddad050d62a8'	System	06 Aug 2020 15:10:44
User entered 'Yes (Y)'	System	06 Aug 2020 15:10:44

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:10:20', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '899ddd40-9b1c-4cc7-846c-ddad050d62a8'	System	06 Aug 2020 15:10:44
User entered '97.2'	System	06 Aug 2020 15:10:44

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:10:27', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '899ddd40-9b1c-4cc7-846c-ddad050d62a8'	System	06 Aug 2020 15:10:44
User entered 'No (N)'	System	06 Aug 2020 15:10:44

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:10:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '899ddd40-9b1c-4cc7-846c-ddad050d62a8'	System	06 Aug 2020 15:10:44
User entered '06 Aug 2020 11:10'	System	06 Aug 2020 15:10:44



US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Aug 2020 10:46'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Aug 2020 13:16'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:51:04', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1e95c6dd-2ba9-4f88-ac33-99d50b719422'	System	06 Aug 2020 22:51:34
User entered 'Yes (Y)'	System	06 Aug 2020 22:51:34

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:51:19', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1e95c6dd-2ba9-4f88-ac33-99d50b719422'	System	06 Aug 2020 22:51:34
User entered '98.0'	System	06 Aug 2020 22:51:34

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:51:24', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1e95c6dd-2ba9-4f88-ac33-99d50b719422'	System	06 Aug 2020 22:51:34
User entered 'No (N)'	System	06 Aug 2020 22:51:34

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:51:33', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1e95c6dd-2ba9-4f88-ac33-99d50b719422'	System	06 Aug 2020 22:51:34
User entered '06 Aug 2020 18:51'	System	06 Aug 2020 22:51:34

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Aug 2020 14:11'	System	06 Aug 2020 14:32:43



US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 2'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:24:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ce65d57c-74b6-440a-a7d7-f97026a3184f'	System	07 Aug 2020 22:24:46
User entered 'Yes (Y)'	System	07 Aug 2020 22:24:46

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:24:23', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ce65d57c-74b6-440a-a7d7-f97026a3184f' User entered '98.7'	System	07 Aug 2020 22:24:46
	System	07 Aug 2020 22:24:46

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:24:30', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ce65d57c-74b6-440a-a7d7-f97026a3184f'	System	07 Aug 2020 22:24:46
User entered 'No (N)'	System	07 Aug 2020 22:24:46

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:24:43', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ce65d57c-74b6-440a-a7d7-f97026a3184f'	System	07 Aug 2020 22:24:46
User entered '07 Aug 2020 18:24'	System	07 Aug 2020 22:24:46

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:32:43



US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 3'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:02:02', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6087e0ac-cc4f-4c79-9d6a-035c244a1a7b'	System	08 Aug 2020 22:02:36
User entered 'Yes (Y)'	System	08 Aug 2020 22:02:36

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:02:28', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6087e0ac-cc4f-4c79-9d6a-035c244a1a7b'	System	08 Aug 2020 22:02:36
User entered '97.6'	System	08 Aug 2020 22:02:36

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:02:17', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6087e0ac-cc4f-4c79-9d6a-035c244a1a7b'	System	08 Aug 2020 22:02:36
User entered 'No (N)'	System	08 Aug 2020 22:02:36

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:02:32', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6087e0ac-cc4f-4c79-9d6a-035c244a1a7b'	System	08 Aug 2020 22:02:36
User entered '08 Aug 2020 18:02'	System	08 Aug 2020 22:02:36

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 4'	System	06 Aug 2020 14:32:43



US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:12:33', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ee31f066-0d19-45f3-a7a3-d95552c816cc'	System	09 Aug 2020 22:12:56
User entered 'Yes (Y)'	System	09 Aug 2020 22:12:56

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:12:43', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ee31f066-0d19-45f3-a7a3-d95552c816cc'	System	09 Aug 2020 22:12:56
User entered '97.7'	System	09 Aug 2020 22:12:56

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:12:47', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ee31f066-0d19-45f3-a7a3-d95552c816cc'	System	09 Aug 2020 22:12:56
User entered 'No (N)'	System	09 Aug 2020 22:12:56

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:12:54', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ee31f066-0d19-45f3-a7a3-d95552c816cc'	System	09 Aug 2020 22:12:56
User entered '09 Aug 2020 18:12'	System	09 Aug 2020 22:12:56

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 5'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:00:26', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c9e2ff12-ac8b-4cd8-aac5-02e358d011d1'	System	10 Aug 2020 21:00:51
User entered 'Yes (Y)'	System	10 Aug 2020 21:00:51



US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:00:37', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c9e2ff12-ac8b-4cd8-aac5-02e358d011d1'	System	10 Aug 2020 21:00:51
User entered '97.9'	System	10 Aug 2020 21:00:51

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:00:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c9e2ff12-ac8b-4cd8-aac5-02e358d011d1'	System	10 Aug 2020 21:00:51
User entered 'No (N)'	System	10 Aug 2020 21:00:51

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:00:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c9e2ff12-ac8b-4cd8-aac5-02e358d011d1'	System	10 Aug 2020 21:00:51
User entered '10 Aug 2020 17:00'	System	10 Aug 2020 21:00:51

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 6'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:46:53', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '3a96a25c-edec-4298-8cb9-f6b5b38344a8'	System	11 Aug 2020 21:47:43
User entered 'Yes (Y)'	System	11 Aug 2020 21:47:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:47:04', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '3a96a25c-edec-4298-8cb9-f6b5b38344a8'	System	11 Aug 2020 21:47:43
User entered '97.1'	System	11 Aug 2020 21:47:43



US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:47:09', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '3a96a25c-edec-4298-8cb9-f6b5b38344a8'	System	11 Aug 2020 21:47:43
User entered 'No (N)'	System	11 Aug 2020 21:47:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:47:14', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '3a96a25c-edec-4298-8cb9-f6b5b38344a8'	System	11 Aug 2020 21:47:43
User entered '11 Aug 2020 17:47'	System	11 Aug 2020 21:47:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 7'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:13:37', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0e05760c-c620-4b7f-b2ad-ae520930bb74'	System	12 Aug 2020 23:13:57
User entered 'Yes (Y)'	System	12 Aug 2020 23:13:57

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:13:45', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0e05760c-c620-4b7f-b2ad-ae520930bb74'	System	12 Aug 2020 23:13:57
User entered '97.9'	System	12 Aug 2020 23:13:57

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:13:49', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0e05760c-c620-4b7f-b2ad-ae520930bb74'	System	12 Aug 2020 23:13:57
User entered 'No (N)'	System	12 Aug 2020 23:13:57



US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:13:55', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0e05760c-c620-4b7f-b2ad-ae520930bb74'	System	12 Aug 2020 23:13:57
User entered '12 Aug 2020 19:13'	System	12 Aug 2020 23:13:57

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:11:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ee3100fc-a319-4312-8057-fceed336e47c'	System	06 Aug 2020 15:11:22
User entered 'None (1)'	System	06 Aug 2020 15:11:22

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:10:54', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ee3100fc-a319-4312-8057-fceed336e47c'	System	06 Aug 2020 15:11:22
User entered 'No (N)'	System	06 Aug 2020 15:11:22

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:10:59', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ee3100fc-a319-4312-8057-fceed336e47c'	System	06 Aug 2020 15:11:22
User entered 'No (N)'	System	06 Aug 2020 15:11:22

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:11:05', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ee3100fc-a319-4312-8057-fceed336e47c'	System	06 Aug 2020 15:11:22
User entered 'None (1)'	System	06 Aug 2020 15:11:22



US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:11:20', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'ee3100fc-a319-4312-8057-fceed336e47c'	System	06 Aug 2020 15:11:22
User entered '06 Aug 2020 11:11'	System	06 Aug 2020 15:11:22

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Aug 2020 10:46'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Aug 2020 13:16'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:47:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7c9ef6f0-ad8e-4450-925c-b2819deb34b5'	System	06 Aug 2020 22:48:19
User entered 'None (1)'	System	06 Aug 2020 22:48:19

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:47:56', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7c9ef6f0-ad8e-4450-925c-b2819deb34b5'	System	06 Aug 2020 22:48:19
User entered 'No (N)'	System	06 Aug 2020 22:48:19

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:48:00', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7c9ef6f0-ad8e-4450-925c-b2819deb34b5'	System	06 Aug 2020 22:48:19
User entered 'No (N)'	System	06 Aug 2020 22:48:19

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:48:06', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7c9ef6f0-ad8e-4450-925c-b2819deb34b5'	System	06 Aug 2020 22:48:19
User entered 'None (1)'	System	06 Aug 2020 22:48:19



US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:48:14', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7c9ef6f0-ad8e-4450-925c-b2819deb34b5'	System	06 Aug 2020 22:48:19
User entered '06 Aug 2020 18:48'	System	06 Aug 2020 22:48:19

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Aug 2020 14:11'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 2'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:25:05', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0c379eb5-dee5-439c-a309-f01e25db2d4d'	System	07 Aug 2020 22:26:07
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 22:26:07

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:25:10', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0c379eb5-dee5-439c-a309-f01e25db2d4d'	System	07 Aug 2020 22:26:07
User entered 'No (N)'	System	07 Aug 2020 22:26:07

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:25:38', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0c379eb5-dee5-439c-a309-f01e25db2d4d'	System	07 Aug 2020 22:26:07
User entered 'No (N)'	System	07 Aug 2020 22:26:07

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:25:49', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0c379eb5-dee5-439c-a309-f01e25db2d4d'	System	07 Aug 2020 22:26:07
User entered 'None (1)'	System	07 Aug 2020 22:26:07



US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:26:03', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0c379eb5-dee5-439c-a309-f01e25db2d4d'	System	07 Aug 2020 22:26:07
User entered '07 Aug 2020 18:26'	System	07 Aug 2020 22:26:07

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 3'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:02:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4f3f9761-eebf-40d3-9f35-28fa2720fce2'	System	08 Aug 2020 22:03:14
User entered 'None (1)'	System	08 Aug 2020 22:03:14

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:02:47', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4f3f9761-eebf-40d3-9f35-28fa2720fce2'	System	08 Aug 2020 22:03:14
User entered 'No (N)'	System	08 Aug 2020 22:03:14

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:02:51', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4f3f9761-eebf-40d3-9f35-28fa2720fce2'	System	08 Aug 2020 22:03:14
User entered 'No (N)'	System	08 Aug 2020 22:03:14

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:03:01', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4f3f9761-eebf-40d3-9f35-28fa2720fce2'	System	08 Aug 2020 22:03:14
User entered 'None (1)'	System	08 Aug 2020 22:03:14



US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:03:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4f3f9761-eebf-40d3-9f35-28fa2720fce2'	System	08 Aug 2020 22:03:14
User entered '08 Aug 2020 18:03'	System	08 Aug 2020 22:03:14

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 4'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:13:02', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'db1737c1-07c4-4f83-8635-8649af5681ca'	System	09 Aug 2020 22:13:25
User entered 'None (1)'	System	09 Aug 2020 22:13:25

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:13:07', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'db1737c1-07c4-4f83-8635-8649af5681ca'	System	09 Aug 2020 22:13:25
User entered 'No (N)'	System	09 Aug 2020 22:13:25

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:13:10', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'db1737c1-07c4-4f83-8635-8649af5681ca'	System	09 Aug 2020 22:13:25
User entered 'No (N)'	System	09 Aug 2020 22:13:25

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:13:14', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'db1737c1-07c4-4f83-8635-8649af5681ca'	System	09 Aug 2020 22:13:25
User entered 'None (1)'	System	09 Aug 2020 22:13:25



US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:13:23', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'db1737c1-07c4-4f83-8635-8649af5681ca'	System	09 Aug 2020 22:13:25
User entered '09 Aug 2020 18:13'	System	09 Aug 2020 22:13:25

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 5'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:00:58', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b83ca7bc-f174-4fc1-a52f-3c7eb3a0088a'	System	10 Aug 2020 21:01:24
User entered 'None (1)'	System	10 Aug 2020 21:01:24

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:01:04', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b83ca7bc-f174-4fc1-a52f-3c7eb3a0088a'	System	10 Aug 2020 21:01:24
User entered 'No (N)'	System	10 Aug 2020 21:01:24

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:01:07', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b83ca7bc-f174-4fc1-a52f-3c7eb3a0088a'	System	10 Aug 2020 21:01:24
User entered 'No (N)'	System	10 Aug 2020 21:01:24

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:01:14', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b83ca7bc-f174-4fc1-a52f-3c7eb3a0088a'	System	10 Aug 2020 21:01:24
User entered 'None (1)'	System	10 Aug 2020 21:01:24



US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:01:23', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b83ca7bc-f174-4fc1-a52f-3c7eb3a0088a'	System	10 Aug 2020 21:01:24
User entered '10 Aug 2020 17:01'	System	10 Aug 2020 21:01:24

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 6'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:51:37', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8165add5-2bf7-448a-b689-1fc2fe69f233'	System	11 Aug 2020 21:52:07
User entered 'None (1)'	System	11 Aug 2020 21:52:07

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:51:41', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8165add5-2bf7-448a-b689-1fc2fe69f233'	System	11 Aug 2020 21:52:07
User entered 'No (N)'	System	11 Aug 2020 21:52:07

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:51:46', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8165add5-2bf7-448a-b689-1fc2fe69f233'	System	11 Aug 2020 21:52:07
User entered 'No (N)'	System	11 Aug 2020 21:52:07

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:51:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8165add5-2bf7-448a-b689-1fc2fe69f233'	System	11 Aug 2020 21:52:07
User entered 'None (1)'	System	11 Aug 2020 21:52:07



US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:52:01', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8165add5-2bf7-448a-b689-1fc2fe69f233'	System	11 Aug 2020 21:52:07
User entered '11 Aug 2020 17:52'	System	11 Aug 2020 21:52:07

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 7'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:14:13', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '300a6b45-684f-40c7-b968-30c7f8bd6059'	System	12 Aug 2020 23:14:38
User entered 'None (1)'	System	12 Aug 2020 23:14:38

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:14:18', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '300a6b45-684f-40c7-b968-30c7f8bd6059'	System	12 Aug 2020 23:14:38
User entered 'No (N)'	System	12 Aug 2020 23:14:38

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:14:22', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '300a6b45-684f-40c7-b968-30c7f8bd6059'	System	12 Aug 2020 23:14:38
User entered 'No (N)'	System	12 Aug 2020 23:14:38

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:14:26', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '300a6b45-684f-40c7-b968-30c7f8bd6059'	System	12 Aug 2020 23:14:38
User entered 'None (1)'	System	12 Aug 2020 23:14:38



US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:14:35', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '300a6b45-684f-40c7-b968-30c7f8bd6059'	System	12 Aug 2020 23:14:38
User entered '12 Aug 2020 19:14'	System	12 Aug 2020 23:14:38

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:11:27', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70dc52de-fef9-49dc-9232-14d52e3b270e'	System	06 Aug 2020 15:12:30
User entered 'None (0)'	System	06 Aug 2020 15:12:30

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:11:34', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70dc52de-fef9-49dc-9232-14d52e3b270e'	System	06 Aug 2020 15:12:30
User entered 'None (0)'	System	06 Aug 2020 15:12:30

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:11:38', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70dc52de-fef9-49dc-9232-14d52e3b270e'	System	06 Aug 2020 15:12:30
User entered 'None (0)'	System	06 Aug 2020 15:12:30

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:12:06', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70dc52de-fef9-49dc-9232-14d52e3b270e'	System	06 Aug 2020 15:12:30
User entered 'None (0)'	System	06 Aug 2020 15:12:30



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:12:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70dc52de-fef9-49dc-9232-14d52e3b270e'	System	06 Aug 2020 15:12:30
User entered 'None (0)'	System	06 Aug 2020 15:12:30

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:12:16', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70dc52de-fef9-49dc-9232-14d52e3b270e'	System	06 Aug 2020 15:12:30
User entered 'None (0)'	System	06 Aug 2020 15:12:30

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:12:24', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70dc52de-fef9-49dc-9232-14d52e3b270e'	System	06 Aug 2020 15:12:30
User entered 'No (N)'	System	06 Aug 2020 15:12:30

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T11:12:27', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70dc52de-fef9-49dc-9232-14d52e3b270e'	System	06 Aug 2020 15:12:30
User entered '06 Aug 2020 11:12'	System	06 Aug 2020 15:12:30

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Aug 2020 10:46'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Aug 2020 13:16'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:46:53', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '29b71473-179d-4760-8076-59feda30a0b2'	System	06 Aug 2020 22:47:45
User entered 'None (0)'	System	06 Aug 2020 22:47:45



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:46:58', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '29b71473-179d-4760-8076-59feda30a0b2'	System	06 Aug 2020 22:47:45
User entered 'None (0)'	System	06 Aug 2020 22:47:45

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:47:01', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '29b71473-179d-4760-8076-59feda30a0b2'	System	06 Aug 2020 22:47:45
User entered 'None (0)'	System	06 Aug 2020 22:47:45

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:47:08', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '29b71473-179d-4760-8076-59feda30a0b2'	System	06 Aug 2020 22:47:45
User entered 'None (0)'	System	06 Aug 2020 22:47:45

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:47:11', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '29b71473-179d-4760-8076-59feda30a0b2'	System	06 Aug 2020 22:47:45
User entered 'None (0)'	System	06 Aug 2020 22:47:45

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:47:14', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '29b71473-179d-4760-8076-59feda30a0b2'	System	06 Aug 2020 22:47:45
User entered 'None (0)'	System	06 Aug 2020 22:47:45

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:47:28', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '29b71473-179d-4760-8076-59feda30a0b2'	System	06 Aug 2020 22:47:45
User entered 'No (N)'	System	06 Aug 2020 22:47:45

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-06T18:47:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '29b71473-179d-4760-8076-59feda30a0b2'	System	06 Aug 2020 22:47:45
User entered '06 Aug 2020 18:47'	System	06 Aug 2020 22:47:45

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Aug 2020 14:11'	System	06 Aug 2020 14:32:43



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 2'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:26:15', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7b153005-4d3f-4699-b9e8-a1bb0303ac64'	System	07 Aug 2020 22:27:06
User entered 'None (0)'	System	07 Aug 2020 22:27:06

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:26:22', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7b153005-4d3f-4699-b9e8-a1bb0303ac64'	System	07 Aug 2020 22:27:06
User entered 'None (0)'	System	07 Aug 2020 22:27:06

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:26:31', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7b153005-4d3f-4699-b9e8-a1bb0303ac64'	System	07 Aug 2020 22:27:06
User entered 'None (0)'	System	07 Aug 2020 22:27:06

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:26:37', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7b153005-4d3f-4699-b9e8-a1bb0303ac64'	System	07 Aug 2020 22:27:06
User entered 'None (0)'	System	07 Aug 2020 22:27:06

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:26:41', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7b153005-4d3f-4699-b9e8-a1bb0303ac64'	System	07 Aug 2020 22:27:06
User entered 'None (0)'	System	07 Aug 2020 22:27:06

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:26:45', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7b153005-4d3f-4699-b9e8-a1bb0303ac64'	System	07 Aug 2020 22:27:06
User entered 'None (0)'	System	07 Aug 2020 22:27:06



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:26:52', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7b153005-4d3f-4699-b9e8-a1bb0303ac64'	System	07 Aug 2020 22:27:06
User entered 'No (N)'	System	07 Aug 2020 22:27:06

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-07T18:27:02', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7b153005-4d3f-4699-b9e8-a1bb0303ac64'	System	07 Aug 2020 22:27:06
User entered '07 Aug 2020 18:27'	System	07 Aug 2020 22:27:06

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 3'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:03:32', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'cc467d84-66e3-413b-a623-96976cfa11d2'	System	08 Aug 2020 22:04:10
User entered 'None (0)'	System	08 Aug 2020 22:04:10

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:03:36', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'cc467d84-66e3-413b-a623-96976cfa11d2'	System	08 Aug 2020 22:04:10
User entered 'None (0)'	System	08 Aug 2020 22:04:10

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:03:40', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'cc467d84-66e3-413b-a623-96976cfa11d2'	System	08 Aug 2020 22:04:10
User entered 'None (0)'	System	08 Aug 2020 22:04:10



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:03:43', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'cc467d84-66e3-413b-a623-96976cfa11d2'	System	08 Aug 2020 22:04:10
User entered 'None (0)'	System	08 Aug 2020 22:04:10

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:03:46', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'cc467d84-66e3-413b-a623-96976cfa11d2'	System	08 Aug 2020 22:04:10
User entered 'None (0)'	System	08 Aug 2020 22:04:10

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:03:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'cc467d84-66e3-413b-a623-96976cfa11d2'	System	08 Aug 2020 22:04:10
User entered 'None (0)'	System	08 Aug 2020 22:04:10

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:03:58', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'cc467d84-66e3-413b-a623-96976cfa11d2'	System	08 Aug 2020 22:04:10
User entered 'No (N)'	System	08 Aug 2020 22:04:10

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-08T18:04:08', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'cc467d84-66e3-413b-a623-96976cfa11d2'	System	08 Aug 2020 22:04:10
User entered '08 Aug 2020 18:04'	System	08 Aug 2020 22:04:10

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 4'	System	06 Aug 2020 14:32:43



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:11:44', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d6bcc0b-4e44-4a2b-8a13-269973ef79ab'	System	09 Aug 2020 22:12:14
User entered 'None (0)'	System	09 Aug 2020 22:12:14

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:11:47', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d6bcc0b-4e44-4a2b-8a13-269973ef79ab'	System	09 Aug 2020 22:12:14
User entered 'None (0)'	System	09 Aug 2020 22:12:14

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:11:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d6bcc0b-4e44-4a2b-8a13-269973ef79ab'	System	09 Aug 2020 22:12:14
User entered 'None (0)'	System	09 Aug 2020 22:12:14

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:11:54', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d6bcc0b-4e44-4a2b-8a13-269973ef79ab'	System	09 Aug 2020 22:12:14
User entered 'None (0)'	System	09 Aug 2020 22:12:14

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:11:57', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d6bcc0b-4e44-4a2b-8a13-269973ef79ab'	System	09 Aug 2020 22:12:14
User entered 'None (0)'	System	09 Aug 2020 22:12:14

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:11:59', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d6bcc0b-4e44-4a2b-8a13-269973ef79ab'	System	09 Aug 2020 22:12:14
User entered 'None (0)'	System	09 Aug 2020 22:12:14

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:12:05', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d6bcc0b-4e44-4a2b-8a13-269973ef79ab'	System	09 Aug 2020 22:12:14
User entered 'No (N)'	System	09 Aug 2020 22:12:14

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-09T18:12:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d6bcc0b-4e44-4a2b-8a13-269973ef79ab'	System	09 Aug 2020 22:12:14
User entered '09 Aug 2020 18:12'	System	09 Aug 2020 22:12:14



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 5'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:01:34', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1cbc7a15-c479-4ddc-b58b-1b9e5a3b1f5e'	System	10 Aug 2020 21:02:15
User entered 'None (0)'	System	10 Aug 2020 21:02:15

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:01:37', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1cbc7a15-c479-4ddc-b58b-1b9e5a3b1f5e'	System	10 Aug 2020 21:02:15
User entered 'None (0)'	System	10 Aug 2020 21:02:15

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:01:43', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1cbc7a15-c479-4ddc-b58b-1b9e5a3b1f5e'	System	10 Aug 2020 21:02:15
User entered 'None (0)'	System	10 Aug 2020 21:02:15

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:01:53', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1cbc7a15-c479-4ddc-b58b-1b9e5a3b1f5e'	System	10 Aug 2020 21:02:15
User entered 'None (0)'	System	10 Aug 2020 21:02:15

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:01:57', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1cbc7a15-c479-4ddc-b58b-1b9e5a3b1f5e'	System	10 Aug 2020 21:02:15
User entered 'None (0)'	System	10 Aug 2020 21:02:15



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:02:00', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1cbc7a15-c479-4ddc-b58b-1b9e5a3b1f5e'	System	10 Aug 2020 21:02:15
User entered 'None (0)'	System	10 Aug 2020 21:02:15

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:02:05', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1cbc7a15-c479-4ddc-b58b-1b9e5a3b1f5e'	System	10 Aug 2020 21:02:15
User entered 'No (N)'	System	10 Aug 2020 21:02:15

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-10T17:02:13', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '1cbc7a15-c479-4ddc-b58b-1b9e5a3b1f5e'	System	10 Aug 2020 21:02:15
User entered '10 Aug 2020 17:02'	System	10 Aug 2020 21:02:15

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 6'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:52:11', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a35a7dc7-4b91-4df6-a5f9-41b9e4f14988'	System	11 Aug 2020 21:52:49
User entered 'None (0)'	System	11 Aug 2020 21:52:49

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:52:15', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a35a7dc7-4b91-4df6-a5f9-41b9e4f14988'	System	11 Aug 2020 21:52:49
User entered 'None (0)'	System	11 Aug 2020 21:52:49



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:52:18', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a35a7dc7-4b91-4df6-a5f9-41b9e4f14988'	System	11 Aug 2020 21:52:49
User entered 'None (0)'	System	11 Aug 2020 21:52:49

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:52:21', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a35a7dc7-4b91-4df6-a5f9-41b9e4f14988'	System	11 Aug 2020 21:52:49
User entered 'None (0)'	System	11 Aug 2020 21:52:49

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:52:25', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a35a7dc7-4b91-4df6-a5f9-41b9e4f14988'	System	11 Aug 2020 21:52:49
User entered 'None (0)'	System	11 Aug 2020 21:52:49

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:52:28', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a35a7dc7-4b91-4df6-a5f9-41b9e4f14988'	System	11 Aug 2020 21:52:49
User entered 'None (0)'	System	11 Aug 2020 21:52:49

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:52:35', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a35a7dc7-4b91-4df6-a5f9-41b9e4f14988'	System	11 Aug 2020 21:52:49
User entered 'No (N)'	System	11 Aug 2020 21:52:49

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-11T17:52:45', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a35a7dc7-4b91-4df6-a5f9-41b9e4f14988'	System	11 Aug 2020 21:52:49
User entered '11 Aug 2020 17:52'	System	11 Aug 2020 21:52:49

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:32:43



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 7'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:14:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eb9fdcc2-2443-4d77-91e7-79c4a87319d7'	System	12 Aug 2020 23:15:33
User entered 'None (0)'	System	12 Aug 2020 23:15:33

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:14:46', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eb9fdcc2-2443-4d77-91e7-79c4a87319d7'	System	12 Aug 2020 23:15:33
User entered 'None (0)'	System	12 Aug 2020 23:15:33

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:14:51', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eb9fdcc2-2443-4d77-91e7-79c4a87319d7'	System	12 Aug 2020 23:15:33
User entered 'None (0)'	System	12 Aug 2020 23:15:33

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:15:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eb9fdcc2-2443-4d77-91e7-79c4a87319d7'	System	12 Aug 2020 23:15:33
User entered 'None (0)'	System	12 Aug 2020 23:15:33

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:15:15', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eb9fdcc2-2443-4d77-91e7-79c4a87319d7'	System	12 Aug 2020 23:15:33
User entered 'None (0)'	System	12 Aug 2020 23:15:33

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:15:18', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eb9fdcc2-2443-4d77-91e7-79c4a87319d7'	System	12 Aug 2020 23:15:33
User entered 'None (0)'	System	12 Aug 2020 23:15:33

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:15:22', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eb9fdcc2-2443-4d77-91e7-79c4a87319d7'	System	12 Aug 2020 23:15:33
User entered 'No (N)'	System	12 Aug 2020 23:15:33



US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-08-12T19:15:29', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eb9fdcc2-2443-4d77-91e7-79c4a87319d7'	System	12 Aug 2020 23:15:33
User entered '12 Aug 2020 19:15'	System	12 Aug 2020 23:15:33

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:32:43

US3202025

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:19:19

US3202025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '13 Aug 2020'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:19:19
	(b) (4)	

US3202025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:19:19

US3202025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	Lilian Nukuna (b) (4)	21 Aug 2020 21:19:19

US3202025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:19:33



US3202025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'I'	System	21 Aug 2020 21:19:33

US3202025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:19:48

US3202025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '21 Aug 2020'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:19:48
	(b) (4)	

US3202025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:19:48

US3202025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	Lilian Nukuna (b) (4)	21 Aug 2020 21:19:48

US3202025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 16:41:42

US3202025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'I'	System	03 Sep 2020 16:41:42

US3202025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:06:21



US3202025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
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)	23 Oct 2020 13:35:40
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 'date recorded on source' (Site from System).	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:07:01
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	13 Sep 2020 15:06:21
User entered '31 Aug 2020'	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:06:21

US3202025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:06:21

US3202025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:06:21

US3202025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 16:41:47

US3202025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'I'	System	03 Sep 2020 16:41:47

US3202025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 16:41:57

US3202025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 16:41:57

US3202025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 16:41:57



US3202025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'VISIT2'	System	03 Sep 2020 16:41:57

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '03 Sep 2020'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '11:34'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '03 Sep 2020 11:34'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '36.8' C	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35



US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '80'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35
	(b) (4)	

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'bpm'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '14'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'breaths/min'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '125'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'mmHg'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '66'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35



US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'mmHg'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35
	(b) (4)	

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '03 Sep 2020'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '13:00'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '03 Sep 2020 13:00'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '36.9' C	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35
	(b) (4)	



US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '78'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35
	(b) (4)	

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'bpm'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '14'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'breaths/min'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '112'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'mmHg'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '80'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:04:35



US3202025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'mmHg'	System	13 Sep 2020 15:04:35

US3202025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:20:47

US3202025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:20:47

US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 16:42:33

US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 16:42:33

US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	Tiffany Jewell (b) (4)	03 Sep 2020 16:42:33

US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 16:42:33

US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 16:42:33



US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '12:19'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 16:42:33

US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '3 Sep 2020 12:19'	System	03 Sep 2020 16:42:33

US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	03 Sep 2020 16:42:41
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	03 Sep 2020 16:42:41
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 16:42:41
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	03 Sep 2020 16:42:33
User entered 'Right Arm (RIGHT ARM)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 16:42:33

US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'ONCE'	System	03 Sep 2020 16:42:33

US3202025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 16:42:33

US3202025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:21:01

US3202025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:21:01

US3202025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '11:50'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:21:01



US3202025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '3 Sep 2020 11:50'	System	04 Sep 2020 18:21:01

US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:39:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '3 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:21:15

US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	04 Sep 2020 18:21:15

US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:21:15

US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '11:46'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:21:15

US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '3 Sep 2020 11:46'	System	04 Sep 2020 18:21:15

US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	04 Sep 2020 18:21:15

US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:21:15



US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:21:15

US3202025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered empty.	System	04 Sep 2020 18:21:15

US3202025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	04 Sep 2020 18:21:25

US3202025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'I'	System	04 Sep 2020 18:21:25

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:06:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'f8cccc03-c33e-42dc-b5f9-bb045d1b1a33'	System	03 Sep 2020 17:07:38
User entered 'Yes (Y)'	System	03 Sep 2020 17:07:38

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:07:15', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'f8cccc03-c33e-42dc-b5f9-bb045d1b1a33'	System	03 Sep 2020 17:07:38
User entered '98.5'	System	03 Sep 2020 17:07:38

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:07:20', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'f8cccc03-c33e-42dc-b5f9-bb045d1b1a33'	System	03 Sep 2020 17:07:38
User entered 'No (N)'	System	03 Sep 2020 17:07:38



US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:07:32', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'f8cccc03-c33e-42dc-b5f9-bb045d1b1a33'	System	03 Sep 2020 17:07:38
User entered '03 Sep 2020 13:07'	System	03 Sep 2020 17:07:38

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '03 Sep 2020 12:39'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '03 Sep 2020 15:09'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:00', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '441e6dfb-64a6-44a3-bb07-dbad6efed076'	System	03 Sep 2020 20:40:21
User entered 'Yes (Y)'	System	03 Sep 2020 20:40:21

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:07', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '441e6dfb-64a6-44a3-bb07-dbad6efed076'	System	03 Sep 2020 20:40:21
User entered '97.5'	System	03 Sep 2020 20:40:21

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '441e6dfb-64a6-44a3-bb07-dbad6efed076'	System	03 Sep 2020 20:40:21
User entered 'No (N)'	System	03 Sep 2020 20:40:21

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:19', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '441e6dfb-64a6-44a3-bb07-dbad6efed076'	System	03 Sep 2020 20:40:21
User entered '03 Sep 2020 16:40'	System	03 Sep 2020 20:40:21



US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '03 Sep 2020 16:04'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 2'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:55:28', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'fc752986-f424-4cad-ae91-688cb4051a29'	System	04 Sep 2020 21:55:54
User entered 'Yes (Y)'	System	04 Sep 2020 21:55:54

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:55:37', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'fc752986-f424-4cad-ae91-688cb4051a29'	System	04 Sep 2020 21:55:54
User entered '99.0'	System	04 Sep 2020 21:55:54

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:55:44', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'fc752986-f424-4cad-ae91-688cb4051a29'	System	04 Sep 2020 21:55:54
User entered 'No (N)'	System	04 Sep 2020 21:55:54

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:55:51', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'fc752986-f424-4cad-ae91-688cb4051a29'	System	04 Sep 2020 21:55:54
User entered '04 Sep 2020 17:55'	System	04 Sep 2020 21:55:54

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:42:33



US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 3'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:17:08', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a3c995e4-3d60-49cb-9779-7b98846815d2'	System	05 Sep 2020 23:17:34
User entered 'Yes (Y)'	System	05 Sep 2020 23:17:34

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:17:17', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a3c995e4-3d60-49cb-9779-7b98846815d2'	System	05 Sep 2020 23:17:34
User entered '98.5'	System	05 Sep 2020 23:17:34

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:17:24', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a3c995e4-3d60-49cb-9779-7b98846815d2'	System	05 Sep 2020 23:17:34
User entered 'No (N)'	System	05 Sep 2020 23:17:34

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:17:30', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a3c995e4-3d60-49cb-9779-7b98846815d2'	System	05 Sep 2020 23:17:34
User entered '05 Sep 2020 19:17'	System	05 Sep 2020 23:17:34

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:42:33



US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 4'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:00:59', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6ae31ab0-1edd-4a2a-9aa5-d6ca676ff7b8'	System	06 Sep 2020 20:01:25
User entered 'Yes (Y)'	System	06 Sep 2020 20:01:25

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:01:10', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6ae31ab0-1edd-4a2a-9aa5-d6ca676ff7b8'	System	06 Sep 2020 20:01:25
User entered '98.0'	System	06 Sep 2020 20:01:25

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:01:16', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6ae31ab0-1edd-4a2a-9aa5-d6ca676ff7b8'	System	06 Sep 2020 20:01:25
User entered 'No (N)'	System	06 Sep 2020 20:01:25

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:01:22', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6ae31ab0-1edd-4a2a-9aa5-d6ca676ff7b8'	System	06 Sep 2020 20:01:25
User entered '06 Sep 2020 16:01'	System	06 Sep 2020 20:01:25

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 5'	System	03 Sep 2020 16:42:33



US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:48:30', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4fa87f34-a9de-41e9-9ef9-0080bc8f4f84'	System	07 Sep 2020 20:48:55
User entered 'Yes (Y)'	System	07 Sep 2020 20:48:55

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:48:40', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4fa87f34-a9de-41e9-9ef9-0080bc8f4f84'	System	07 Sep 2020 20:48:55
User entered '98.0'	System	07 Sep 2020 20:48:55

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:48:44', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4fa87f34-a9de-41e9-9ef9-0080bc8f4f84'	System	07 Sep 2020 20:48:55
User entered 'No (N)'	System	07 Sep 2020 20:48:55

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:48:51', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4fa87f34-a9de-41e9-9ef9-0080bc8f4f84'	System	07 Sep 2020 20:48:55
User entered '07 Sep 2020 16:48'	System	07 Sep 2020 20:48:55

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 6'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:01', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0c29818f-fde3-4612-9d68-992ac1b76155'	System	08 Sep 2020 19:32:20
User entered 'Yes (Y)'	System	08 Sep 2020 19:32:20



US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:08', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0c29818f-fde3-4612-9d68-992ac1b76155'	System	08 Sep 2020 19:32:20
User entered '99.2'	System	08 Sep 2020 19:32:20

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:13', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0c29818f-fde3-4612-9d68-992ac1b76155'	System	08 Sep 2020 19:32:20
User entered 'No (N)'	System	08 Sep 2020 19:32:20

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:18', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0c29818f-fde3-4612-9d68-992ac1b76155'	System	08 Sep 2020 19:32:20
User entered '08 Sep 2020 15:32'	System	08 Sep 2020 19:32:20

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 7'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:30:09', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '78edcc2b-87e5-4426-8046-b13280216cbe'	System	10 Sep 2020 01:30:36
User entered 'Yes (Y)'	System	10 Sep 2020 01:30:36

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:30:28', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '78edcc2b-87e5-4426-8046-b13280216cbe'	System	10 Sep 2020 01:30:36
User entered '99.2'	System	10 Sep 2020 01:30:36



US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:30:21', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '78edcc2b-87e5-4426-8046-b13280216cbe'	System	10 Sep 2020 01:30:36
User entered 'No (N)'	System	10 Sep 2020 01:30:36

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:30:31', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '78edcc2b-87e5-4426-8046-b13280216cbe'	System	10 Sep 2020 01:30:36
User entered '09 Sep 2020 21:30'	System	10 Sep 2020 01:30:36

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:07:40', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'bac01277-8e66-48ef-b3a5-8fb4ee86303c'	System	03 Sep 2020 17:07:56
User entered 'None (1)'	System	03 Sep 2020 17:07:56

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:07:43', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'bac01277-8e66-48ef-b3a5-8fb4ee86303c'	System	03 Sep 2020 17:07:56
User entered 'No (N)'	System	03 Sep 2020 17:07:56

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:07:46', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'bac01277-8e66-48ef-b3a5-8fb4ee86303c'	System	03 Sep 2020 17:07:56
User entered 'No (N)'	System	03 Sep 2020 17:07:56



US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:07:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'bac01277-8e66-48ef-b3a5-8fb4ee86303c'	System	03 Sep 2020 17:07:56
User entered 'None (1)'	System	03 Sep 2020 17:07:56

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:07:54', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'bac01277-8e66-48ef-b3a5-8fb4ee86303c'	System	03 Sep 2020 17:07:56
User entered '03 Sep 2020 13:07'	System	03 Sep 2020 17:07:56

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '03 Sep 2020 12:39'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '03 Sep 2020 15:09'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:31', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '806e79fc-c453-49c3-8881-74344f9caf76'	System	03 Sep 2020 20:40:54
User entered 'None (1)'	System	03 Sep 2020 20:40:54

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:34', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '806e79fc-c453-49c3-8881-74344f9caf76'	System	03 Sep 2020 20:40:54
User entered 'No (N)'	System	03 Sep 2020 20:40:54

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:38', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '806e79fc-c453-49c3-8881-74344f9caf76'	System	03 Sep 2020 20:40:54
User entered 'No (N)'	System	03 Sep 2020 20:40:54



US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '806e79fc-c453-49c3-8881-74344f9caf76'	System	03 Sep 2020 20:40:54
User entered 'None (1)'	System	03 Sep 2020 20:40:54

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:49', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '806e79fc-c453-49c3-8881-74344f9caf76'	System	03 Sep 2020 20:40:54
User entered '03 Sep 2020 16:40'	System	03 Sep 2020 20:40:54

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '03 Sep 2020 16:04'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 2'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:56:16', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e5a75314-db02-4c4d-a616-961b39f0fe56'	System	04 Sep 2020 21:56:44
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 21:56:44

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:56:22', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e5a75314-db02-4c4d-a616-961b39f0fe56'	System	04 Sep 2020 21:56:44
User entered 'No (N)'	System	04 Sep 2020 21:56:44

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:56:27', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e5a75314-db02-4c4d-a616-961b39f0fe56'	System	04 Sep 2020 21:56:44
User entered 'No (N)'	System	04 Sep 2020 21:56:44



US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:56:32', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e5a75314-db02-4c4d-a616-961b39f0fe56'	System	04 Sep 2020 21:56:44
User entered 'None (1)'	System	04 Sep 2020 21:56:44

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:56:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e5a75314-db02-4c4d-a616-961b39f0fe56'	System	04 Sep 2020 21:56:44
User entered '04 Sep 2020 17:56'	System	04 Sep 2020 21:56:44

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 3'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:17:47', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e4dd8e36-ba76-406d-a463-cbacdcc5bee7'	System	05 Sep 2020 23:19:10
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:19:10

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:17:53', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e4dd8e36-ba76-406d-a463-cbacdcc5bee7'	System	05 Sep 2020 23:19:10
User entered 'No (N)'	System	05 Sep 2020 23:19:10

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:18:25', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e4dd8e36-ba76-406d-a463-cbacdcc5bee7'	System	05 Sep 2020 23:19:10
User entered 'No (N)'	System	05 Sep 2020 23:19:10



US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:18:53', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e4dd8e36-ba76-406d-a463-cbacdcc5bee7'	System	05 Sep 2020 23:19:10
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:19:10

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:19:06', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e4dd8e36-ba76-406d-a463-cbacdcc5bee7'	System	05 Sep 2020 23:19:10
User entered '05 Sep 2020 19:19'	System	05 Sep 2020 23:19:10

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 4'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:01:32', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a405051b-9715-4d94-9fbb-691ec4e30b31'	System	06 Sep 2020 20:02:11
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 20:02:11

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:01:37', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a405051b-9715-4d94-9fbb-691ec4e30b31'	System	06 Sep 2020 20:02:11
User entered 'No (N)'	System	06 Sep 2020 20:02:11

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:01:43', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a405051b-9715-4d94-9fbb-691ec4e30b31'	System	06 Sep 2020 20:02:11
User entered 'No (N)'	System	06 Sep 2020 20:02:11



US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:01:58', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a405051b-9715-4d94-9fbb-691ec4e30b31'	System	06 Sep 2020 20:02:11
User entered 'None (1)'	System	06 Sep 2020 20:02:11

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:02:10', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a405051b-9715-4d94-9fbb-691ec4e30b31'	System	06 Sep 2020 20:02:11
User entered '06 Sep 2020 16:02'	System	06 Sep 2020 20:02:11

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 5'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:03', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '9f71f012-31c1-46ef-a39a-34c1ac6a57cd'	System	07 Sep 2020 20:49:24
User entered 'None (1)'	System	07 Sep 2020 20:49:24

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:08', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '9f71f012-31c1-46ef-a39a-34c1ac6a57cd'	System	07 Sep 2020 20:49:24
User entered 'No (N)'	System	07 Sep 2020 20:49:24

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:11', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '9f71f012-31c1-46ef-a39a-34c1ac6a57cd'	System	07 Sep 2020 20:49:24
User entered 'No (N)'	System	07 Sep 2020 20:49:24



US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:16', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '9f71f012-31c1-46ef-a39a-34c1ac6a57cd'	System	07 Sep 2020 20:49:24
User entered 'None (1)'	System	07 Sep 2020 20:49:24

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:23', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '9f71f012-31c1-46ef-a39a-34c1ac6a57cd'	System	07 Sep 2020 20:49:24
User entered '07 Sep 2020 16:49'	System	07 Sep 2020 20:49:24

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 6'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:26', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd529718e-f3b7-4a20-92e1-2b34489c126e'	System	08 Sep 2020 19:32:48
User entered 'None (1)'	System	08 Sep 2020 19:32:48

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:29', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd529718e-f3b7-4a20-92e1-2b34489c126e'	System	08 Sep 2020 19:32:48
User entered 'No (N)'	System	08 Sep 2020 19:32:48

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:32', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd529718e-f3b7-4a20-92e1-2b34489c126e'	System	08 Sep 2020 19:32:48
User entered 'No (N)'	System	08 Sep 2020 19:32:48



US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:39', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd529718e-f3b7-4a20-92e1-2b34489c126e'	System	08 Sep 2020 19:32:48
User entered 'None (1)'	System	08 Sep 2020 19:32:48

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:46', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd529718e-f3b7-4a20-92e1-2b34489c126e'	System	08 Sep 2020 19:32:48
User entered '08 Sep 2020 15:32'	System	08 Sep 2020 19:32:48

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 7'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:30:40', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0cfa200a-eaef-4a91-bf47-131fa2f618d7'	System	10 Sep 2020 01:30:57
User entered 'None (1)'	System	10 Sep 2020 01:30:57

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:30:43', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0cfa200a-eaef-4a91-bf47-131fa2f618d7'	System	10 Sep 2020 01:30:57
User entered 'No (N)'	System	10 Sep 2020 01:30:57

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:30:47', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0cfa200a-eaef-4a91-bf47-131fa2f618d7'	System	10 Sep 2020 01:30:57
User entered 'No (N)'	System	10 Sep 2020 01:30:57



US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:30:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0cfa200a-eaef-4a91-bf47-131fa2f618d7'	System	10 Sep 2020 01:30:57
User entered 'None (1)'	System	10 Sep 2020 01:30:57

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:30:56', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0cfa200a-eaef-4a91-bf47-131fa2f618d7'	System	10 Sep 2020 01:30:57
User entered '09 Sep 2020 21:30'	System	10 Sep 2020 01:30:57

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:08:02', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70fd3354-7a76-428c-98ed-f0c0b3b14b81'	System	03 Sep 2020 17:08:27
User entered 'None (0)'	System	03 Sep 2020 17:08:27

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:08:05', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70fd3354-7a76-428c-98ed-f0c0b3b14b81'	System	03 Sep 2020 17:08:27
User entered 'None (0)'	System	03 Sep 2020 17:08:27

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:08:07', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70fd3354-7a76-428c-98ed-f0c0b3b14b81'	System	03 Sep 2020 17:08:27
User entered 'None (0)'	System	03 Sep 2020 17:08:27



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:08:09', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70fd3354-7a76-428c-98ed-f0c0b3b14b81'	System	03 Sep 2020 17:08:27
User entered 'None (0)'	System	03 Sep 2020 17:08:27

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:08:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70fd3354-7a76-428c-98ed-f0c0b3b14b81'	System	03 Sep 2020 17:08:27
User entered 'None (0)'	System	03 Sep 2020 17:08:27

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:08:15', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70fd3354-7a76-428c-98ed-f0c0b3b14b81'	System	03 Sep 2020 17:08:27
User entered 'None (0)'	System	03 Sep 2020 17:08:27

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:08:19', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70fd3354-7a76-428c-98ed-f0c0b3b14b81'	System	03 Sep 2020 17:08:27
User entered 'No (N)'	System	03 Sep 2020 17:08:27

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T13:08:25', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '70fd3354-7a76-428c-98ed-f0c0b3b14b81'	System	03 Sep 2020 17:08:27
User entered '03 Sep 2020 13:08'	System	03 Sep 2020 17:08:27

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '03 Sep 2020 12:39'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '03 Sep 2020 15:09'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:42:33



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:40:58', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b47954b5-37fd-4ca3-970f-3ac5a9c353ec'	System	03 Sep 2020 20:41:28
User entered 'None (0)'	System	03 Sep 2020 20:41:28

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:41:01', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b47954b5-37fd-4ca3-970f-3ac5a9c353ec'	System	03 Sep 2020 20:41:28
User entered 'None (0)'	System	03 Sep 2020 20:41:28

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:41:04', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b47954b5-37fd-4ca3-970f-3ac5a9c353ec'	System	03 Sep 2020 20:41:28
User entered 'None (0)'	System	03 Sep 2020 20:41:28

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:41:06', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b47954b5-37fd-4ca3-970f-3ac5a9c353ec'	System	03 Sep 2020 20:41:28
User entered 'None (0)'	System	03 Sep 2020 20:41:28

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:41:09', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b47954b5-37fd-4ca3-970f-3ac5a9c353ec'	System	03 Sep 2020 20:41:28
User entered 'None (0)'	System	03 Sep 2020 20:41:28

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:41:11', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b47954b5-37fd-4ca3-970f-3ac5a9c353ec'	System	03 Sep 2020 20:41:28
User entered 'None (0)'	System	03 Sep 2020 20:41:28

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:41:19', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b47954b5-37fd-4ca3-970f-3ac5a9c353ec'	System	03 Sep 2020 20:41:28
User entered 'No (N)'	System	03 Sep 2020 20:41:28

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-03T16:41:25', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'b47954b5-37fd-4ca3-970f-3ac5a9c353ec'	System	03 Sep 2020 20:41:28
User entered '03 Sep 2020 16:41'	System	03 Sep 2020 20:41:28



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '03 Sep 2020 16:04'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 2'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:57:05', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '314b164e-8668-4992-b5d1-cc6ce014635e'	System	04 Sep 2020 21:57:50
User entered 'No interference with activity (1)'	System	04 Sep 2020 21:57:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:57:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '314b164e-8668-4992-b5d1-cc6ce014635e'	System	04 Sep 2020 21:57:50
User entered 'None (0)'	System	04 Sep 2020 21:57:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:57:17', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '314b164e-8668-4992-b5d1-cc6ce014635e'	System	04 Sep 2020 21:57:50
User entered 'None (0)'	System	04 Sep 2020 21:57:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:57:23', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '314b164e-8668-4992-b5d1-cc6ce014635e'	System	04 Sep 2020 21:57:50
User entered 'None (0)'	System	04 Sep 2020 21:57:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:57:26', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '314b164e-8668-4992-b5d1-cc6ce014635e'	System	04 Sep 2020 21:57:50
User entered 'None (0)'	System	04 Sep 2020 21:57:50



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:57:30', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '314b164e-8668-4992-b5d1-cc6ce014635e'	System	04 Sep 2020 21:57:50
User entered 'None (0)'	System	04 Sep 2020 21:57:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:57:36', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '314b164e-8668-4992-b5d1-cc6ce014635e'	System	04 Sep 2020 21:57:50
User entered 'No (N)'	System	04 Sep 2020 21:57:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-04T17:57:45', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '314b164e-8668-4992-b5d1-cc6ce014635e'	System	04 Sep 2020 21:57:50
User entered '04 Sep 2020 17:57'	System	04 Sep 2020 21:57:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 3'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:19:13', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7ea3fc2d-f9ba-4a1b-b304-165049f29da2'	System	05 Sep 2020 23:19:54
User entered 'None (0)'	System	05 Sep 2020 23:19:54

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:19:24', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7ea3fc2d-f9ba-4a1b-b304-165049f29da2'	System	05 Sep 2020 23:19:54
User entered 'None (0)'	System	05 Sep 2020 23:19:54



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:19:28', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7ea3fc2d-f9ba-4a1b-b304-165049f29da2'	System	05 Sep 2020 23:19:54
User entered 'None (0)'	System	05 Sep 2020 23:19:54

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:19:32', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7ea3fc2d-f9ba-4a1b-b304-165049f29da2'	System	05 Sep 2020 23:19:54
User entered 'None (0)'	System	05 Sep 2020 23:19:54

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:19:35', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7ea3fc2d-f9ba-4a1b-b304-165049f29da2'	System	05 Sep 2020 23:19:54
User entered 'None (0)'	System	05 Sep 2020 23:19:54

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:19:39', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7ea3fc2d-f9ba-4a1b-b304-165049f29da2'	System	05 Sep 2020 23:19:54
User entered 'None (0)'	System	05 Sep 2020 23:19:54

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:19:43', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7ea3fc2d-f9ba-4a1b-b304-165049f29da2'	System	05 Sep 2020 23:19:54
User entered 'No (N)'	System	05 Sep 2020 23:19:54

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-05T19:19:52', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '7ea3fc2d-f9ba-4a1b-b304-165049f29da2'	System	05 Sep 2020 23:19:54
User entered '05 Sep 2020 19:19'	System	05 Sep 2020 23:19:54

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:42:33



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 4'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:02:16', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5844d803-c8b3-45d2-833e-ad3d07fcfc23'	System	06 Sep 2020 20:02:50
User entered 'None (0)'	System	06 Sep 2020 20:02:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:02:19', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5844d803-c8b3-45d2-833e-ad3d07fcfc23'	System	06 Sep 2020 20:02:50
User entered 'None (0)'	System	06 Sep 2020 20:02:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:02:23', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5844d803-c8b3-45d2-833e-ad3d07fcfc23'	System	06 Sep 2020 20:02:50
User entered 'None (0)'	System	06 Sep 2020 20:02:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:02:27', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5844d803-c8b3-45d2-833e-ad3d07fcfc23'	System	06 Sep 2020 20:02:50
User entered 'None (0)'	System	06 Sep 2020 20:02:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:02:30', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5844d803-c8b3-45d2-833e-ad3d07fcfc23'	System	06 Sep 2020 20:02:50
User entered 'None (0)'	System	06 Sep 2020 20:02:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:02:33', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5844d803-c8b3-45d2-833e-ad3d07fcfc23'	System	06 Sep 2020 20:02:50
User entered 'None (0)'	System	06 Sep 2020 20:02:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:02:38', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5844d803-c8b3-45d2-833e-ad3d07fcfc23'	System	06 Sep 2020 20:02:50
User entered 'No (N)'	System	06 Sep 2020 20:02:50



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-06T16:02:47', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5844d803-c8b3-45d2-833e-ad3d07fcfc23'	System	06 Sep 2020 20:02:50
User entered '06 Sep 2020 16:02'	System	06 Sep 2020 20:02:50

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 5'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:31', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '188a317f-8c0a-4637-82bf-9027060977c1' User entered 'None (0)'	System	07 Sep 2020 20:50:08
	System	07 Sep 2020 20:50:08

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:34', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '188a317f-8c0a-4637-82bf-9027060977c1'	System	07 Sep 2020 20:50:08
User entered 'None (0)'	System	07 Sep 2020 20:50:08

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:38', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '188a317f-8c0a-4637-82bf-9027060977c1'	System	07 Sep 2020 20:50:08
User entered 'None (0)'	System	07 Sep 2020 20:50:08

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:41', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '188a317f-8c0a-4637-82bf-9027060977c1'	System	07 Sep 2020 20:50:08
User entered 'None (0)'	System	07 Sep 2020 20:50:08



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:45', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '188a317f-8c0a-4637-82bf-9027060977c1'	System	07 Sep 2020 20:50:08
User entered 'None (0)'	System	07 Sep 2020 20:50:08

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:48', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '188a317f-8c0a-4637-82bf-9027060977c1'	System	07 Sep 2020 20:50:08
User entered 'None (0)'	System	07 Sep 2020 20:50:08

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:49:59', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '188a317f-8c0a-4637-82bf-9027060977c1'	System	07 Sep 2020 20:50:08
User entered 'No (N)'	System	07 Sep 2020 20:50:08

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-07T16:50:07', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '188a317f-8c0a-4637-82bf-9027060977c1'	System	07 Sep 2020 20:50:08
User entered '07 Sep 2020 16:50'	System	07 Sep 2020 20:50:08

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 6'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:32:55', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aae821d1-3717-46b0-9b79-850facd0a920'	System	08 Sep 2020 19:33:55
User entered 'None (0)'	System	08 Sep 2020 19:33:55



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:33:05', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aae821d1-3717-46b0-9b79-850facd0a920'	System	08 Sep 2020 19:33:55
User entered 'None (0)'	System	08 Sep 2020 19:33:55

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:33:18', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aae821d1-3717-46b0-9b79-850facd0a920'	System	08 Sep 2020 19:33:55
User entered 'No interference with activity (1)'	System	08 Sep 2020 19:33:55

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:33:30', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aae821d1-3717-46b0-9b79-850facd0a920'	System	08 Sep 2020 19:33:55
User entered 'No interference with activity (1)'	System	08 Sep 2020 19:33:55

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:33:35', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aae821d1-3717-46b0-9b79-850facd0a920'	System	08 Sep 2020 19:33:55
User entered 'None (0)'	System	08 Sep 2020 19:33:55

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:33:37', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aae821d1-3717-46b0-9b79-850facd0a920'	System	08 Sep 2020 19:33:55
User entered 'None (0)'	System	08 Sep 2020 19:33:55

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:33:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aae821d1-3717-46b0-9b79-850facd0a920'	System	08 Sep 2020 19:33:55
User entered 'No (N)'	System	08 Sep 2020 19:33:55

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-08T15:33:52', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aae821d1-3717-46b0-9b79-850facd0a920'	System	08 Sep 2020 19:33:55
User entered '08 Sep 2020 15:33'	System	08 Sep 2020 19:33:55

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:42:33



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	03 Sep 2020 16:42:33
User entered 'Day 7'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:31:12', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '221dff83-938c-48cf-8235-1d5e398f9f20'	System	10 Sep 2020 01:31:44
User entered 'No interference with activity (1)'	System	10 Sep 2020 01:31:44

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:31:15', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '221dff83-938c-48cf-8235-1d5e398f9f20'	System	10 Sep 2020 01:31:44
User entered 'None (0)'	System	10 Sep 2020 01:31:44

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:31:23', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '221dff83-938c-48cf-8235-1d5e398f9f20'	System	10 Sep 2020 01:31:44
User entered 'None (0)'	System	10 Sep 2020 01:31:44

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:31:26', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '221dff83-938c-48cf-8235-1d5e398f9f20'	System	10 Sep 2020 01:31:44
User entered 'None (0)'	System	10 Sep 2020 01:31:44

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:31:28', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '221dff83-938c-48cf-8235-1d5e398f9f20'	System	10 Sep 2020 01:31:44
User entered 'None (0)'	System	10 Sep 2020 01:31:44

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:31:31', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '221dff83-938c-48cf-8235-1d5e398f9f20'	System	10 Sep 2020 01:31:44
User entered 'None (0)'	System	10 Sep 2020 01:31:44



US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:31:35', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '221dff83-938c-48cf-8235-1d5e398f9f20'	System	10 Sep 2020 01:31:44
User entered 'No (N)'	System	10 Sep 2020 01:31:44

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-09T21:31:44', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '221dff83-938c-48cf-8235-1d5e398f9f20'	System	10 Sep 2020 01:31:44
User entered '09 Sep 2020 21:31'	System	10 Sep 2020 01:31:44

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:42:33

US3202025

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	10 Sep 2020 01:31:44
User entered 'Day 8'	System	10 Sep 2020 01:31:44

US3202025

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:39:33

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-10T13:32:28', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '3ccf175a-9375-4681-8559-732ee67827fe'	System	10 Sep 2020 17:33:09
User entered 'None (0)'	System	10 Sep 2020 17:33:09

US3202025

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:39:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-10T13:32:34', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '3ccf175a-9375-4681-8559-732ee67827fe'	System	10 Sep 2020 17:33:09
User entered '10 Sep 2020 13:32'	System	10 Sep 2020 17:33:09

US3202025

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 01:31:44



US3202025

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 01:31:44

US3202025

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	08 Sep 2020 19:33:55
User entered 'Day 8'	System	08 Sep 2020 19:33:55

US3202025

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-10T13:32:59', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eea998a3-8807-4f8a-a500-9a10af6cb0f9'	System	10 Sep 2020 17:33:18
User entered 'No (N)'	System	10 Sep 2020 17:33:18

US3202025

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:39:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-09-10T13:33:03', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'eea998a3-8807-4f8a-a500-9a10af6cb0f9' User entered '10 Sep 2020 13:33'	System	10 Sep 2020 17:33:18
	System	10 Sep 2020 17:33:18

US3202025

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:39:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:33:55

US3202025

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:39:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:33:55

US3202025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:05:24

US3202025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '10 Sep 2020'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:05:24
	(b) (4)	



US3202025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:05:24

US3202025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:05:24

US3202025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	13 Sep 2020 15:05:29

US3202025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'I'	System	13 Sep 2020 15:05:29

US3202025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 14:45:54

US3202025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '18 Sep 2020'	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 14:45:54

US3202025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 14:45:54

US3202025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	Lilian Nukuna (b) (4)	18 Sep 2020 14:45:54



US3202025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	18 Sep 2020 14:46:01

US3202025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'I'	System	18 Sep 2020 14:46:01

US3202025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	25 Sep 2020 12:43:22

US3202025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered '25 Sep 2020'	(b) (4) Lilian Nukuna (b) (4)	25 Sep 2020 12:43:22
	(b) (4)	

US3202025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	25 Sep 2020 12:43:22

US3202025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered empty.	Lilian Nukuna (b) (4)	25 Sep 2020 12:43:22

US3202025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:43:53
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	25 Sep 2020 12:43:27

US3202025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'I'	System	25 Sep 2020 12:43:27



US3202025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:06:38

US3202025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '1 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:06:38

US3202025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:06:38

US3202025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User entered 'VISIT3'	System	02 Oct 2020 15:06:38

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '1 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '09:26'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User entered '1 Oct 2020 09:26'	System	02 Oct 2020 15:09:58



US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	02 Oct 2020 15:10:06
User entered '97.7' F reason for change: Data Entry Error	Tiffany Jewell (b) (4)	02 Oct 2020 15:10:06
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
User entered '97.7' C	System	02 Oct 2020 15:09:58
	Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58
	(b) (4)	

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '71'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User entered 'bpm'	System	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '18'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User entered 'breaths/min'	System	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '124'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58



US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User entered 'mmHg'	System	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '62'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45
User entered 'mmHg'	System	02 Oct 2020 15:09:58

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45

US3202025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:13:45

US3202025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:10:11

US3202025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:10:11

US3202025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:10:27



US3202025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '1 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:10:27

US3202025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered '09:35'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:10:27

US3202025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '1 Oct 2020 09:35'	System	02 Oct 2020 15:10:27

US3202025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:44:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	02 Oct 2020 15:10:31

US3202025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered '1'	System	02 Oct 2020 15:10:31

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 64'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-10-09T12:25:22', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5895972c-3ad9-40bf-bec5-d6585ecb6593'	System	09 Oct 2020 16:25:58
User entered 'No (N)'	System	09 Oct 2020 16:25:58

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-10-09T12:25:33', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5895972c-3ad9-40bf-bec5-d6585ecb6593'	System	09 Oct 2020 16:25:58
User entered 'No (N)'	System	09 Oct 2020 16:25:58



US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-10-09T12:25:54', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5895972c-3ad9-40bf-bec5-d6585ecb6593'	System	09 Oct 2020 16:25:58
User entered '09 Oct 2020 12:25:54'	System	09 Oct 2020 16:25:58

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 71'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-10-16T16:22:28', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0215aed6-c9fb-40ab-a070-d3868f092700'	System	16 Oct 2020 20:22:49
User entered 'No (N)'	System	16 Oct 2020 20:22:49

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-10-16T16:22:39', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0215aed6-c9fb-40ab-a070-d3868f092700'	System	16 Oct 2020 20:22:49
User entered 'No (N)'	System	16 Oct 2020 20:22:49

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-10-16T16:22:45', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '0215aed6-c9fb-40ab-a070-d3868f092700'	System	16 Oct 2020 20:22:49
User entered '16 Oct 2020 16:22:45'	System	16 Oct 2020 20:22:49

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 14:32:43



US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 78'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-10-23T20:28:20', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d909121-277f-4aea-b2c6-dfe2789d6c0f'	System	24 Oct 2020 00:28:55
User entered 'No (N)'	System	24 Oct 2020 00:28:55

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-10-23T20:28:34', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d909121-277f-4aea-b2c6-dfe2789d6c0f'	System	24 Oct 2020 00:28:55
User entered 'No (N)'	System	24 Oct 2020 00:28:55

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-10-23T20:28:49', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8d909121-277f-4aea-b2c6-dfe2789d6c0f' User entered '23 Oct 2020 20:28:49'	System	24 Oct 2020 00:28:55
	System	24 Oct 2020 00:28:55

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 92'	System	06 Aug 2020 14:32:43



US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-11-06T17:17:06', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd096071c-32a5-4965-80ce-764fccbafc9'	System	06 Nov 2020 22:17:28
User entered 'No (N)'	System	06 Nov 2020 22:17:28

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-11-06T17:17:17', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd096071c-32a5-4965-80ce-764fccbafc9'	System	06 Nov 2020 22:17:28
User entered 'No (N)'	System	06 Nov 2020 22:17:28

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-11-06T17:17:23', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd096071c-32a5-4965-80ce-764fcccba9c9'	System	06 Nov 2020 22:17:28
User entered '06 Nov 2020 17:17:23'	System	06 Nov 2020 22:17:28

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 99'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-11-13T14:26:39', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6ab2882f-10dc-4835-9801-3e1904fb58b3'	System	13 Nov 2020 19:27:23
User entered 'Yes (Y)'	System	13 Nov 2020 19:27:23

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-11-13T14:26:48', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6ab2882f-10dc-4835-9801-3e1904fb58b3'	System	13 Nov 2020 19:27:23
User entered 'No (N)'	System	13 Nov 2020 19:27:23



US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-11-13T14:26:58', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6ab2882f-10dc-4835-9801-3e1904fb58b3'	System	13 Nov 2020 19:27:23
User entered 'No (N)'	System	13 Nov 2020 19:27:23

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-11-13T14:27:14', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6ab2882f-10dc-4835-9801-3e1904fb58b3'	System	13 Nov 2020 19:27:23
User entered 'No (N)'	System	13 Nov 2020 19:27:23

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-11-13T14:27:19', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '6ab2882f-10dc-4835-9801-3e1904fb58b3'	System	13 Nov 2020 19:27:23
User entered '13 Nov 2020 14:27:19'	System	13 Nov 2020 19:27:23

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:20:03
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18
Data entry locked.	System	06 Aug 2020 14:32:43
User entered 'Day 106'	System	06 Aug 2020 14:32:43

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Please 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)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[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)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18



US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18



US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Please 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)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[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)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Please 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)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18

US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 14:32:43



US3202025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:14:18
Data entry locked.	System	06 Aug 2020 14:32:43
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 14:32:43

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2020-11-21T14:27:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '103328b4-b01b-4415-8028-3bd4ca1d8ac4'	System	21 Nov 2020 19:28:07
User entered 'No (N)'	System	21 Nov 2020 19:28:07

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2020-11-21T14:27:55', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '103328b4-b01b-4415-8028-3bd4ca1d8ac4'	System	21 Nov 2020 19:28:07
User entered 'No (N)'	System	21 Nov 2020 19:28:07

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-11-21T14:28:01', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '103328b4-b01b-4415-8028-3bd4ca1d8ac4'	System	21 Nov 2020 19:28:07
User entered '21 Nov 2020 14:28:01'	System	21 Nov 2020 19:28:07

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2020-12-02T11:24:29', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e8c4b1fb-8183-4ec4-adc2-a05e6a37e7b0'	System	02 Dec 2020 16:24:56
User entered 'No (N)'	System	02 Dec 2020 16:24:56

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2020-12-02T11:24:41', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e8c4b1fb-8183-4ec4-adc2-a05e6a37e7b0'	System	02 Dec 2020 16:24:56
User entered 'No (N)'	System	02 Dec 2020 16:24:56

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-12-02T11:24:51', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'e8c4b1fb-8183-4ec4-adc2-a05e6a37e7b0'	System	02 Dec 2020 16:24:56
User entered '02 Dec 2020 11:24:51'	System	02 Dec 2020 16:24:56

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2020-12-09T13:23:04', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'bc0e633c-5e47-481b-9a40-a0bcc495451a'	System	09 Dec 2020 18:23:57
User entered 'No (N)'	System	09 Dec 2020 18:23:57

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2020-12-09T13:23:29', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'bc0e633c-5e47-481b-9a40-a0bcc495451a'	System	09 Dec 2020 18:23:57
User entered 'No (N)'	System	09 Dec 2020 18:23:57



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-12-09T13:23:54', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'bc0e633c-5e47-481b-9a40-a0bcc495451a' User entered '09 Dec 2020 13:23:54'	System	09 Dec 2020 18:23:57
	System	09 Dec 2020 18:23:57

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2020-12-23T08:32:18', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '274a2f3e-b27f-4db9-b553-c952d88b543d'	System	23 Dec 2020 13:32:47
User entered 'No (N)'	System	23 Dec 2020 13:32:47



US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2020-12-23T08:32:29', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '274a2f3e-b27f-4db9-b553-c952d88b543d'	System	23 Dec 2020 13:32:47
User entered 'No (N)'	System	23 Dec 2020 13:32:47

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-12-23T08:32:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '274a2f3e-b27f-4db9-b553-c952d88b543d' User entered '23 Dec 2020 08:32:42'	System	23 Dec 2020 13:32:47
	System	23 Dec 2020 13:32:47

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2020-12-30T19:37:30', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c876cb1c-5ec5-4465-be86-27e94c1a36fb'	System	31 Dec 2020 00:37:52
User entered 'No (N)'	System	31 Dec 2020 00:37:52

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2020-12-30T19:37:41', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c876cb1c-5ec5-4465-be86-27e94c1a36fb'	System	31 Dec 2020 00:37:52
User entered 'No (N)'	System	31 Dec 2020 00:37:52

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2020-12-30T19:37:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c876cb1c-5ec5-4465-be86-27e94c1a36fb' User entered '30 Dec 2020 19:37:50'	System	31 Dec 2020 00:37:52
	System	31 Dec 2020 00:37:52



US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-01-13T22:17:43', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '79af2820-4dcc-4af5-9680-4136062eab2f'	System	14 Jan 2021 03:18:32
User entered 'No (N)'	System	14 Jan 2021 03:18:32

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-01-13T22:17:56', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '79af2820-4dcc-4af5-9680-4136062eab2f'	System	14 Jan 2021 03:18:32
User entered 'No (N)'	System	14 Jan 2021 03:18:32



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-01-13T22:18:26', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '79af2820-4dcc-4af5-9680-4136062eab2f' User entered '13 Jan 2021 22:18:26'	System	14 Jan 2021 03:18:32

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-01-20T10:18:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8a83702a-4c98-4045-b200-aabc4fc6cf81'	System	20 Jan 2021 15:19:07
User entered 'No (N)'	System	20 Jan 2021 15:19:07

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-01-20T10:18:57', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8a83702a-4c98-4045-b200-aabc4fc6cf81'	System	20 Jan 2021 15:19:07
User entered 'No (N)'	System	20 Jan 2021 15:19:07

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-01-20T10:19:03', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8a83702a-4c98-4045-b200-aabc4fc6cf81' User entered '20 Jan 2021 10:19:03'	System	20 Jan 2021 15:19:07
	System	20 Jan 2021 15:19:07

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:14:18

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[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 (c58c191c6ddf5a81)', Time: '2021-01-27T17:05:21', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'f678d7ea-e915-4142-b912-e934dfbd9756'	System	27 Jan 2021 22:06:42
User entered 'No (N)'	System	27 Jan 2021 22:06:42

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-01-27T17:06:21', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'f678d7ea-e915-4142-b912-e934dfbd9756'	System	27 Jan 2021 22:06:42
User entered 'No (N)'	System	27 Jan 2021 22:06:42

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-01-27T17:06:36', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'f678d7ea-e915-4142-b912-e934dfbd9756'	System	27 Jan 2021 22:06:42
User entered '27 Jan 2021 17:06:36'	System	27 Jan 2021 22:06:42

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-02-10T11:34:19', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5262e6fa-bc5b-4713-9af1-12a84fcf4c2f'	System	10 Feb 2021 16:34:57
User entered 'No (N)'	System	10 Feb 2021 16:34:57

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-02-10T11:34:33', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5262e6fa-bc5b-4713-9af1-12a84fcf4c2f'	System	10 Feb 2021 16:34:57
User entered 'No (N)'	System	10 Feb 2021 16:34:57

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-02-10T11:34:52', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '5262e6fa-bc5b-4713-9af1-12a84fcf4c2f' User entered '10 Feb 2021 11:34:52'	System	10 Feb 2021 16:34:57
	System	10 Feb 2021 16:34:57

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-03-02T11:34:23', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4ec5f5cc-82e5-4f68-b2d0-ff157b20ad8b'	System	02 Mar 2021 16:34:39
User entered 'No (N)'	System	02 Mar 2021 16:34:39



US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-03-02T11:34:31', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4ec5f5cc-82e5-4f68-b2d0-ff157b20ad8b'	System	02 Mar 2021 16:34:39
User entered 'No (N)'	System	02 Mar 2021 16:34:39

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-03-02T11:34:36', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4ec5f5cc-82e5-4f68-b2d0-ff157b20ad8b'	System	02 Mar 2021 16:34:39
User entered '02 Mar 2021 11:34:36'	System	02 Mar 2021 16:34:39

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-03-09T10:40:50', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4998bf25-dafe-4be3-baf5-97f6df74f542'	System	09 Mar 2021 15:41:14
User entered 'No (N)'	System	09 Mar 2021 15:41:14

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-03-09T10:41:01', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4998bf25-dafe-4be3-baf5-97f6df74f542'	System	09 Mar 2021 15:41:14
User entered 'No (N)'	System	09 Mar 2021 15:41:14

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-03-09T10:41:08', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '4998bf25-dafe-4be3-baf5-97f6df74f542'	System	09 Mar 2021 15:41:14
User entered '09 Mar 2021 10:41:08'	System	09 Mar 2021 15:41:14



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-03-17T18:51:01', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aea323ce-b19d-44b1-991b-af3047cf5832'	System	17 Mar 2021 22:51:42
User entered 'No (N)'	System	17 Mar 2021 22:51:42

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-03-17T18:51:26', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aea323ce-b19d-44b1-991b-af3047cf5832'	System	17 Mar 2021 22:51:42
User entered 'No (N)'	System	17 Mar 2021 22:51:42

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-03-17T18:51:40', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'aea323ce-b19d-44b1-991b-af3047cf5832' User entered '17 Mar 2021 18:51:40'	System	17 Mar 2021 22:51:42

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-03-24T10:10:44', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c617abb6-7493-438e-b15e-61cd748cfab4'	System	24 Mar 2021 14:11:11
User entered 'No (N)'	System	24 Mar 2021 14:11:11

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-03-24T10:11:00', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c617abb6-7493-438e-b15e-61cd748cfab4'	System	24 Mar 2021 14:11:11
User entered 'No (N)'	System	24 Mar 2021 14:11:11

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-03-24T10:11:05', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'c617abb6-7493-438e-b15e-61cd748cfab4'	System	24 Mar 2021 14:11:11
User entered '24 Mar 2021 10:11:05'	System	24 Mar 2021 14:11:11

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:14:18

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-04-07T12:01:45', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd609fdcf-a088-495a-b7b6-e6f62d7474f9'	System	07 Apr 2021 16:08:19
User entered 'No (N)'	System	07 Apr 2021 16:08:19

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-04-07T12:01:49', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd609fdfc-a088-495a-b7b6-e6f62d7474f9'	System	07 Apr 2021 16:08:19
User entered 'No (N)'	System	07 Apr 2021 16:08:19

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-04-07T12:01:59', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'd609fdcf-a088-495a-b7b6-e6f62d7474f9'	System	07 Apr 2021 16:08:19
User entered '07 Apr 2021 12:01:59'	System	07 Apr 2021 16:08:19

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-04-14T21:37:42', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a1e200ba-04de-4103-a20e-27c986ec7ec4'	System	15 Apr 2021 01:38:04
User entered 'No (N)'	System	15 Apr 2021 01:38:04

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-04-14T21:37:47', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a1e200ba-04de-4103-a20e-27c986ec7ec4'	System	15 Apr 2021 01:38:04
User entered 'No (N)'	System	15 Apr 2021 01:38:04

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-04-14T21:37:55', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: 'a1e200ba-04de-4103-a20e-27c986ec7ec4'	System	15 Apr 2021 01:38:04
User entered '14 Apr 2021 21:37:55'	System	15 Apr 2021 01:38:04

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-04-21T08:07:14', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '3b03a548-ea5e-4367-9c9d-3253e4d5f3e9'	System	21 Apr 2021 12:07:29
User entered 'No (N)'	System	21 Apr 2021 12:07:29

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-04-21T08:07:16', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '3b03a548-ea5e-4367-9c9d-3253e4d5f3e9'	System	21 Apr 2021 12:07:29
User entered 'No (N)'	System	21 Apr 2021 12:07:29



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-04-21T08:07:21', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '3b03a548-ea5e-4367-9c9d-3253e4d5f3e9'	System	21 Apr 2021 12:07:29
User entered '21 Apr 2021 08:07:21'	System	21 Apr 2021 12:07:29

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-04-28T10:46:35', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '446bb7ae-6b67-4ddd-ae34-a7f05831b838'	System	29 Apr 2021 02:05:06
User entered 'Yes (Y)'	System	29 Apr 2021 02:05:06

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

Have you been exposed to someone with 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 (c58c191c6ddf5a81)', Time: '2021-04-28T10:46:46', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '446bb7ae-6b67-4ddd-ae34-a7f05831b838'	System	29 Apr 2021 02:05:06
User entered 'No (N)'	System	29 Apr 2021 02:05:06

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[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 (c58c191c6ddf5a81)', Time: '2021-04-28T10:46:57', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '446bb7ae-6b67-4ddd-ae34-a7f05831b838'	System	29 Apr 2021 02:05:06
User entered 'No (N)'	System	29 Apr 2021 02:05:06

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[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 (c58c191c6ddf5a81)', Time: '2021-04-28T10:47:15', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '446bb7ae-6b67-4ddd-ae34-a7f05831b838'	System	29 Apr 2021 02:05:06
User entered 'Yes (Y)'	System	29 Apr 2021 02:05:06



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-04-28T10:47:41', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '446bb7ae-6b67-4ddd-ae34-a7f05831b838'	System	29 Apr 2021 02:05:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Apr 2021 02:05:06

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-04-28T10:47:55', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '446bb7ae-6b67-4ddd-ae34-a7f05831b838'	System	29 Apr 2021 02:05:06
User entered '28 Apr 2021 10:47:55'	System	29 Apr 2021 02:05:06

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:14:18



US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:14:18



US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:14:18

US3202025

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:14:18

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:14:18

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:14:18



US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:14:18

US3202025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:14:18



US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:14:18



**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:14:18

US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:14:18



US3202025

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:14:18

**US3202025**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:14:18
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:14:18



US3202025

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:39:33**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-03-02T11:33:46', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8beae821-be3e-4cc7-9a5b-c9398bb397c2'	System	02 Mar 2021 16:34:04
User entered 'No (N)'	System	02 Mar 2021 16:34:04

US3202025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:39:33

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:49:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c58c191c6ddf5a81)', Time: '2021-03-02T11:33:59', User OID: 'PatientReportedOutcome (US3202025)', ODM File OID: '8beae821-be3e-4cc7-9a5b-c9398bb397c2'	System	02 Mar 2021 16:34:04
User entered '02 Mar 2021 11:33:59'	System	02 Mar 2021 16:34:04

US3202025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:36:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:35:28

US3202025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:36:28
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:35:28

US3202025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:36:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:35:28

US3202025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:36:28
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:35:28

US3202025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:36:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:35:34

US3202025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:12:43
User entered 'I'	System	30 Oct 2020 17:35:34



US3202025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:04:54

US3202025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:04:54

US3202025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:04:54

US3202025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:04:54

US3202025

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:04:57

US3202025

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User entered 'I'	System	02 Dec 2020 16:04:57

US3202025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	04 Jan 2021 13:54:11

US3202025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '4 Jan 2021'	Lilian Nukuna (b) (4)	04 Jan 2021 13:54:11



US3202025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4)	04 Jan 2021 13:54:11

US3202025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Left a voice message'	Lilian Nukuna (b) (4)	04 Jan 2021 13:54:11

US3202025

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	04 Jan 2021 13:55:12

US3202025

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User entered 'I'	System	04 Jan 2021 13:55:12

US3202025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	02 Feb 2021 21:35:18

US3202025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '2 Feb 2021'	Lilian Nukuna (b) (4)	02 Feb 2021 21:35:18

US3202025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	02 Feb 2021 21:35:18

US3202025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	Lilian Nukuna (b) (4)	02 Feb 2021 21:35:18



US3202025

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	02 Feb 2021 21:35:24

US3202025

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:13:36
User entered 'I'	System	02 Feb 2021 21:35:24

US3202025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	03 Mar 2021 14:19:31

US3202025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '3 Mar 2021'	Lilian Nukuna (b) (4)	03 Mar 2021 14:19:31

US3202025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Clinic (Clinic)'	Lilian Nukuna (b) (4)	03 Mar 2021 14:19:31

US3202025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User entered 'VISIT4'	System	03 Mar 2021 14:19:31

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27
	(b) (4)	

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27
	(b) (4)	



US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27
	(b) (4)	

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User entered empty.	System	30 Mar 2021 18:44:27

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27
	(b) (4)	

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27
	(b) (4)	

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User entered empty.	System	30 Mar 2021 18:44:27

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27



US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User entered empty.	System	30 Mar 2021 18:44:27

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User entered empty.	System	30 Mar 2021 18:44:27

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Mar 2021 18:44:27

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User entered empty.	System	30 Mar 2021 18:44:27

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59

US3202025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59

US3202025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'No (N)'	Lilian Nukuna (b) (4)	03 Mar 2021 14:19:39



US3202025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered empty.	Lilian Nukuna (b) (4)	03 Mar 2021 14:19:39

US3202025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	03 Mar 2021 14:19:54

US3202025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '3 Mar 2021'	Lilian Nukuna (b) (4)	03 Mar 2021 14:19:54

US3202025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '09:12'	Lilian Nukuna (b) (4)	03 Mar 2021 14:19:54

US3202025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User entered '3 Mar 2021 09:12'	System	03 Mar 2021 14:19:54

US3202025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	03 Mar 2021 14:20:01

US3202025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:55:59
User entered 'I'	System	03 Mar 2021 14:20:01

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:07



US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '22 Jan 2021'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:07

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:07

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 18:19:07

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '22 Jan 2021'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:51

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:52:23
User entered '0'	(b) (4) Teresa Deese (b) (4)	22 Apr 2021 14:46:09
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:20:08

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:51

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark McKenzie (b) (4)	22 Apr 2021 18:30:42 22 Apr 2021 17:52:23
Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	22 Apr 2021 14:46:29
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 14:46:09
User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:12:45
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:20:08

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '22 Jan 2021'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:51



US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:51

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:51

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:51

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:19:51

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User entered empty.	System	22 Jan 2021 18:19:51

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:33

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User entered empty.	System	22 Jan 2021 18:19:51

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:20:04

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '22 Jan 2021'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:20:04



US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '09:53'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:20:04

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User entered '22 Jan 2021 09:53'	System	22 Jan 2021 18:20:04

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:39:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:20:17

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:39:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '22 Jan 2021'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:20:17

US3202025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:39:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered '09:51'	(b) (4) Teresa Deese (b) (4)	22 Jan 2021 18:20:17

**US3202025**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:39:33**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:04
User entered '22 Jan 2021 09:51'	System	22 Jan 2021 18:20:17

US3202025

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:39:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:10:18
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 22:17:53
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Data hard locked.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:39:13
Signature has been broken.	Teresa Deese (b) (4)	29 Apr 2021 13:37:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Apr 2021 13:37:27
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:01:03
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:36:23

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 18:32:34
User entered		
'USA-US128-2021-mRNA-1273-P301000021'	System	29 Apr 2021 18:32:28
User entered 'New'	(b) (4), (b) (6)	29 Apr 2021 18:32:28



US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 13:41:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 13:41:57
	(b) (4)	
Data point term sent to Coder	System	29 Apr 2021 13:41:03
User entered 'worsening of back pain'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered '28 Apr 2021'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

**US3202025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35



US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

**US3202025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	29 Apr 2021 13:41:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Apr 2021 13:41:18
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	29 Apr 2021 13:40:35
User entered 'No (N)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 10:29:01
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospital d/c date unknown at this time' (Site from System).	Teresa Deese (b) (4)	29 Apr 2021 13:41:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Apr 2021 13:40:35
User entered '1'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35



US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered '28 Apr 2021'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35



US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'I'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'Unknown (UNKNOWN)'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Apr 2021 13:40:35

US3202025

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
	(b) (4)	
User entered 'subj left VM yesterday stating he was going to hospital b/c of back pain. when contacted this am, stated was being prepped for back surgery at time of call. no other details are known at this time as this was not a good time for subj to answer lot of questions. records have been requested.'	Teresa Deese (b) (4)	29 Apr 2021 13:40:35



**US3202025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:41:18
User entered '0'	System	29 Apr 2021 13:40:35

**US3202025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 13:40:35

**US3202025**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 13:40:35

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 15:39:33**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:57:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:24:48

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 03:31:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 03:31:54
Data point term sent to Coder	System	16 Sep 2020 03:31:23
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 03:31:09
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 03:31:09
User entered 'METFORMIN' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:31:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 07:54:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 07:54:41
Data point term sent to Coder	System	13 Sep 2020 14:50:15
Coding entries removed.	zackery harmon (b) (4)	13 Sep 2020 14:49:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 10:46:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 10:46:36

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	22 Aug 2020 15:26:00
User entered 'Metforman'	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Sep 2020 21:51:09
User entered 'TYPE 2 DIABETES' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:31:09
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	13 Sep 2020 14:49:32
User entered 'DM T2' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	13 Sep 2020 14:49:21
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:19:55
User entered 'sugar control'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:25:46



US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '500'	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'unknown (UNKNOWN)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:25:46

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'un UNK 2011'	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:25:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:25:46

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:25:46

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:25:46

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 03:31:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 03:31:53
Data point term sent to Coder Coding entries removed.	System Erica Osmundsen (b) (4)	16 Sep 2020 03:31:23 16 Sep 2020 03:30:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 04:42:35
User coded data point as Term Coded data point by User: (b) (4) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 04:42:35
Data point term sent to Coder User entered 'atorvastatin'	System zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:27:00 22 Aug 2020 15:26:46



US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 15:27:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Aug 2020 15:27:01
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4)	22 Aug 2020 15:27:01
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 15:26:46
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:19:04
User entered 'HYPERLIPiDEMA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:30:48
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'fixed' (Site from DM).	zackery harmon (b) (4) (b) (4)	13 Sep 2020 14:50:27
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:28:45
User entered 'hyperlipedema'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:26:46

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '40'	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'unknown (UNKNOWN)'	(b) (4) zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'un UNK 2011'	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:26:46
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:26:46

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:26:46



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:26:46

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 03:31:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 03:31:54
Data point term sent to Coder Coding entries removed.	System Erica Osmundsen (b) (4)	16 Sep 2020 03:31:23 16 Sep 2020 03:30:25
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 03:30:25
User entered 'LISINOPRIL/HCTZ' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:30:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 07:21:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 07:21:43
Data point term sent to Coder Coding entries removed.	System zackery harmon (b) (4)	13 Sep 2020 14:52:16 13 Sep 2020 14:52:08

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 10:44:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 10:44:36
Data point term sent to Coder	System	22 Aug 2020 15:29:07
User entered 'Lisinopril/HTZ'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:28:12

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:19:25
User entered 'hypertension' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:30:25
Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	zackery harmon (b) (4)	13 Sep 2020 14:52:16
User entered 'HTN' reason for change: Data Entry Error	zackery harmon (b) (4)	13 Sep 2020 14:52:08
User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:22:48
User entered 'blood pressure'	zackery harmon (b) (4)	22 Aug 2020 15:28:12

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '20/12.5'	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	



US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'unknown (UNKNOWN)'	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'un UNK 2011'	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:28:12
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:28:12

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:28:12

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:28:12

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Sep 2020 14:58:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 14:58:01
Data point term sent to Coder Coding entries removed.	System zackery harmon (b) (4)	13 Sep 2020 14:56:17 13 Sep 2020 14:55:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Aug 2020 07:24:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 07:24:29
Data point term sent to Coder User entered 'Sertraline'	System zackery harmon (b) (4)	22 Aug 2020 15:29:07 22 Aug 2020 15:28:52

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:42:47
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	13 Sep 2020 14:56:15
User entered 'Anxiety' reason for change: New Information	zackery harmon (b) (4) (b) (4)	13 Sep 2020 14:55:39
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:21:20
User entered 'calming'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:28:52

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '50'	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	zackery harmon (b) (4)	13 Sep 2020 14:57:24
User entered 'unknown (UNKNOWN)'	(b) (4)	
	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'un UNK 2015'	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:28:52
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 14:57:24
User entered empty.	System	22 Aug 2020 15:28:52

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 14:57:24
User entered empty.	System	22 Aug 2020 15:28:52

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Sep 2020 14:57:24
User entered empty.	System	22 Aug 2020 15:28:52

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 03:35:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 03:35:49
Data point term sent to Coder	System	16 Sep 2020 03:34:24
Data point term sent to Coder	System	16 Sep 2020 03:30:22
Coding entries removed.	Erica Osmundsen (b) (4)	16 Sep 2020 03:29:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 10:59:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 10:59:44
Data point term sent to Coder	System	13 Sep 2020 15:01:24
Coding entries removed.	zackery harmon (b) (4)	13 Sep 2020 15:00:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 10:25:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 10:25:34
Data point term sent to Coder	System	22 Aug 2020 15:30:07

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Clopidogrel'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:29:31



US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:20:03
User entered 'coronary artery disease' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:34:07
User entered 'HYPERLIPIDEMA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:29:49
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated to reflect it was reported by the pt that they take it for their cholesterol ' (Site from DM).	zackery harmon (b) (4)	13 Sep 2020 15:01:23
User entered 'HYPERLIPIDEMA as reported by patient' reason for change: Data Entry Error	zackery harmon (b) (4)	13 Sep 2020 15:00:59
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:24:41
Query 'HYPERLIPIDEMA ' canceled (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:24:10
User opened query 'HYPERLIPIDEMA ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:24:05
User entered 'hyperlipidema'	zackery harmon (b) (4)	22 Aug 2020 15:29:31

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '75'	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'once daily (QD)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:34:07
User entered 'unknown (UNKNOWN)'	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'un UNK 2008'	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:29:31
	(b) (4)	

**US3202025**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 03:34:07
User entered empty.	System	22 Aug 2020 15:29:31

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 03:34:07
User entered empty.	System	22 Aug 2020 15:29:31



**US3202025**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 03:34:07
User entered empty.	System	22 Aug 2020 15:29:31

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 03:30:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 03:30:52
Data point term sent to Coder Coding entries removed.	System Erica Osmundsen (b) (4)	16 Sep 2020 03:29:22 16 Sep 2020 03:29:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 11:38:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 11:38:46
Data point term sent to Coder Coding entries removed.	System zackery harmon (b) (4)	13 Sep 2020 15:02:24 13 Sep 2020 15:01:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 17:48:15

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'januvia'	Coder Import (b) (4) (b) (4) System zackery harmon (b) (4) (b) (4)	22 Aug 2020 17:48:15  22 Aug 2020 15:31:08 22 Aug 2020 15:30:08

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Sep 2020 22:01:11
User entered 'type 2 diabetes' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:29:19
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:01:51
User entered 'DM T2' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:01:45
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:20:51
User entered 'sugar control'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:30:08

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '100'	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	



US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User entered 'unknown (UNKNOWN)'	(b) (4) zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:30:08

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'un UNK 2014'	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:30:08
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:30:08

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:30:08

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:30:08

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 03:30:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 03:30:52
Data point term sent to Coder Coding entries removed.	System Erica Osmundsen (b) (4)	16 Sep 2020 03:29:22 16 Sep 2020 03:28:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 03:44:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 03:44:36
Data point term sent to Coder Coding entries removed.	System zackery harmon (b) (4)	13 Sep 2020 15:02:24 13 Sep 2020 15:02:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 17:15:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 17:15:13
Data point term sent to Coder User entered 'Gabapentin'	System zackery harmon (b) (4)	22 Aug 2020 15:31:08 22 Aug 2020 15:30:51

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:20:20
User entered 'chronic back pain' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:28:56
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:02:31
User entered 'Pain control indication back surgery' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:02:22
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:27:25
User entered 'back sugery'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:30:51

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '300'	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'four times daily (QID)'	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'un UNK 2014'	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	



US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:30:51
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Aug 2020 15:30:51

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 15:30:51

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 15:30:51

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 11:52:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 11:52:54
Data point term sent to Coder	System	16 Sep 2020 03:29:22
Data point term sent to Coder	System	13 Sep 2020 15:03:24
Coding entries removed.	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:02:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 10:34:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 10:34:31
Data point term sent to Coder	System	22 Aug 2020 15:33:09
User entered 'Hydroco/acetamino'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:32:15

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	



US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
User closed query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:20:27
User entered 'chronic back pain' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Sep 2020 03:28:24
Query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:03:00
User entered 'PAIN from back surgery' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	13 Sep 2020 15:02:57
User opened query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 15:25:02
User entered 'pain'	zackery harmon (b) (4) (b) (4)	22 Aug 2020 15:32:15

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '7.5/325'	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'four times daily (QID)'	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Oral (ORAL)'	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	



US3202025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'un UNK 2014'	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:32:15
	(b) (4)	

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Aug 2020 15:32:15

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 15:32:15

US3202025

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 15:32:15



US3202025

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 15:39:33**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:16:48
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	22 Aug 2020 15:36:15
	(b) (4)	

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'USA-US128-2021-MRNA-1273-P301000021'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'Yes (Y)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'Yes (Y)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28



US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'Mark'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'McKenzie'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
User entered 'US'	(b) (4) System	29 Apr 2021 18:33:01

**US3202025**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 18:33:01

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'USA-US128-2021-MRNA-1273-P301000021'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'Yes (Y)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28



US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'Yes (Y)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'No (N)'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'Mark'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:32:52
User entered 'McKenzie'	System	29 Apr 2021 18:32:28

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
User entered 'US'	(b) (4) System	29 Apr 2021 18:33:01



**US3202025**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 18:33:01

**US3202025**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000021**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:39:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
User entered '29/Apr/2021 14:32'	(b) (4) System	29 Apr 2021 18:33:01

US3202025

Folder: SAE USA-US128-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:39:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	03 May 2021 19:42:41
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:33:01