

US3112113 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:09:10

All time stamps listed in this document are displayed in GMT

US3112113

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:59:02

Generated On: 09 Jun 2021 15:09:10

[Participant ID](#)

US3112113

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

US3112113

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

Date of Informed Consent (*dd MMM yyyy*) 5 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3112113

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

Were any significant conditions reported?

Yes ☒

No ☐

US3112113

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	
Stop Year (derived)	

US3112113

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	LEFT KNEE OSTEOARTHRITIS
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)	

US3112113

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	RIGHT KNEE OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3112113

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	TOTAL RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	LEFT CHRONIC KNEE 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)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	
Stop Year (derived)	

US3112113

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	CONSTIPATION
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 (11)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	NEURALGIA
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)	

US3112113

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3112113

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:55 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 12:55
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	326 lb
BMI (<i>xxx.x</i>)	51.16558 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 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: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

Date of assessment (dd MMM yyyy) 5 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:45:00

Generated On: 09 Jun 2021 15:09:10

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

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

What was the participant's randomization number? 142922

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 ☒

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Height	ND - Not Done
Weight	ND - Not Done

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

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)	5 AUG 2020
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 12:55
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 AUG 2020
Time of assessment (00:00-23:59)	15:32 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 15:32
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	092 mmHg
Diastolic Blood Pressure units	MMHG

US3112113

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 5 AUG 2020

What was the treatment time? (00:00-23:59) 14:58 (24 HR)

Treatment Date and Time (derived) 5 AUG 2020 14:58

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 AUG 2020
Collection time (00:00-23:59)	14:18 (24 HR)
Collection date and time (derived)	5 AUG 2020 14:18

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Collection date (dd MMM yyyy)			5 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:59	5 AUG 2020 13:59
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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 97.7 °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):

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

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

PC Time Stamp 05 AUG 2020 15:35

PC Open Date & Time 05 AUG 2020 15:18

PC Close Date & Time 05 AUG 2020 17:48

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	05 AUG 2020 22:09
PC Open Date & Time	05 AUG 2020 18:43
PC Close Date & Time	06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 11:46

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 22:23

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

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

08 AUG 2020 22:54

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

09 AUG 2020 18:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

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 11:12

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 19:59

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 15:36

PC Open Date & Time

05 AUG 2020 15:18

PC Close Date & Time

05 AUG 2020 17:48

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

3

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 22:13

PC Open Date & Time

05 AUG 2020 18:43

PC Close Date & Time

06 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

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 09:50

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 22:23

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 22:54

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

09 AUG 2020 18:27

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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 11:13

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

11 AUG 2020 19:59

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 15:37
PC Open Date & Time	05 AUG 2020 15:18
PC Close Date & Time	05 AUG 2020 17:48

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 22:13
PC Open Date & Time	05 AUG 2020 18:43
PC Close Date & Time	06 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

		Yes <input type="checkbox"/>
PC Time stamp	07 AUG 2020 09:52	
PC Open Date & Time	06 AUG 2020 12:00	
PC Close Date & Time	07 AUG 2020 11:59	

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

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 ☒

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 22:24
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 22:55
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:28
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

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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US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 11:13
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

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 ☒

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 12 AUG 2020 15:51

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

13 AUG 2020 22:32

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:15

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

16 AUG 2020 17:34

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 18 AUG 2020 10:06

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 AUG 2020 23:59

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

19 AUG 2020 23:59

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

20 AUG 2020 14:02

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

22 AUG 2020 15:55

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

23 AUG 2020 13:21

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

24 AUG 2020 13:12

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

25 AUG 2020 12:10

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:15

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

28 AUG 2020 22:45

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:02

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:59

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:09

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

02 SEP 2020 12:23

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 AUG 2020 15:51
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 AUG 2020 22:32
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 AUG 2020 12:15
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 AUG 2020 17:35
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 10:06
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 00:00
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 00:00
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 14:02
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 12:01
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 AUG 2020 15:55
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 13:21
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 AUG 2020 13:12
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 AUG 2020 12:10
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 23

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

No ☐

Yes ☒

PC Time stamp

27 AUG 2020 12:15

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 AUG 2020 22:45
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 AUG 2020 12:02
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 12:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 27

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

No ☒

Yes ☐

PC Time stamp

31 AUG 2020 12:59

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 SEP 2020 12:09
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 12:23
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3112113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:25

Generated On: 09 Jun 2021 15:09:10

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3112113

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:25

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:25

Generated On: 09 Jun 2021 15:09:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3112113

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:25

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:25

Generated On: 09 Jun 2021 15:09:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3112113

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:25

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	11:41 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 11:41
Temperature (xxx.x)	98.7 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	084 mmHg
Diastolic Blood Pressure units	MMHG

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 14:22
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	078 mmHg
Diastolic Blood Pressure units	MMHG

US3112113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 13:47 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 13:47

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

US3112113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 SEP 2020

Collection time (00:00-23:59)

12:25 (24 HR)

Collection date and time (derived)

2 SEP 2020 12:25

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:51	2 SEP 2020 12:51
Nasopharyngeal Swab 2	No		

US3112113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 14:20

PC Open Date & Time

02 SEP 2020 14:07

PC Close Date & Time

02 SEP 2020 16:37

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	02 SEP 2020 21:27
PC Open Date & Time	02 SEP 2020 17:32
PC Close Date & Time	03 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

98.5 °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 19:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

04 SEP 2020 18:57

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

97.6 °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

05 SEP 2020 17:35

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

95.0 °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

08 SEP 2020 12:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 14:22

PC Open Date & Time

02 SEP 2020 14:07

PC Close Date & Time

02 SEP 2020 16:37

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:08

PC Open Date & Time

02 SEP 2020 17:32

PC Close Date & Time

03 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:06

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 18:57

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 17:34

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

06 SEP 2020 23:04

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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 02:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 12:02

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 14:23
PC Open Date & Time	02 SEP 2020 14:07
PC Close Date & Time	02 SEP 2020 16:37

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 21:28
PC Open Date & Time	02 SEP 2020 17:32
PC Close Date & Time	03 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

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 ☒

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:07
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

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 ☒

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 18:58
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 17:35
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

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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US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 02:01
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:03
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3112113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:36:25

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:36:25

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112113

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112113

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 11:35
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

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.

US3112113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 OCT 2020

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

01 OCT 2020 12:00

US3112113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:41

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

07 OCT 2020 16:21:37

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

12 OCT 2020 18:54:52

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 00:04:04
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 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	09 NOV 2020 00:04:57
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 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	16 NOV 2020 00:02:09
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 NOV 2020 03:51:22
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

28 NOV 2020 15:27:53

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

08 DEC 2020 11:04:42

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message 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	13 DEC 2020 09:50:16
Patient Cloud Open Date & Time	11 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
179 of 3340	

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

18 DEC 2020 00:34:50

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 00:02:16

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 04:03:44

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 00:21:33

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

16 JAN 2021 16:37:32

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 00:02:03

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 17:57:47

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

06 FEB 2021 14:59:31

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 02:39:12
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 FEB 2021 00:15:23
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 <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	26 FEB 2021 00:01:53
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

05 MAR 2021 00:04:16

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	12 MAR 2021 00:32:22
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 00:02:08

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 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	26 MAR 2021 08:22:48
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 <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	05 APR 2021 06:15:44
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 12:50:42

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 <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	18 APR 2021 12:41:54
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Patient Cloud Open Date & Time	23 APR 2021 00:01
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Patient Cloud Close Date & Time	27 APR 2021 23:59
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US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 00:01:51

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 <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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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="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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	04 JUN 2021 00:01
Patient Cloud Close Date & Time	08 JUN 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Patient Cloud Open Date & Time	02 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	09 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Patient Cloud Open Date & Time	27 AUG 2021 00:01
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Patient Cloud Close Date & Time	31 AUG 2021 23:59
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US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	03 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 <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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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="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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	29 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 <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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 <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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	18 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	11 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	18 MAR 2022 00:01
Patient Cloud Close Date & Time	22 MAR 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	01 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 <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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	03 JUN 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	01 JUL 2022 00:01
Patient Cloud Close Date & Time	05 JUL 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	12 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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="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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	26 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 <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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	16 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
Patient Cloud Open Date & Time	23 SEP 2022 00:01
Patient Cloud Close Date & Time	27 SEP 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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"/>

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3112113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:09:10

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		01 MAR 2021 02:46:50

US3112113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112113

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:44:48

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3112113

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3112113

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3112113

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT4

US3112113

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

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.

US3112113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3112113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112113

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Date of Contact	14 DEC 2020
Time of Contact	14:30
Date and Time of Contact (derived)	14 DEC 2020 14:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	09 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Date of Visit 14 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 14 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 20:59:05

Generated On: 09 Jun 2021 15:09:10

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 DEC 2020
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3112113

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 DEC 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 15:30
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112113

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3112113

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 DEC 2020

US3112113

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

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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US3112113

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

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 _____

US3112113

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 22 JAN 2021

Collection time (00:00-23:59) 14:10 (24 HR)

Collection date and time (derived) 22 JAN 2021 14:10

US3112113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:59:06

Generated On: 09 Jun 2021 15:09:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	14:06
Collection Date and Time (derived)	22 JAN 2021 14:06

US3112113

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:20:11

Generated On: 09 Jun 2021 15:09:10

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

AEID

Adverse event

RIGHT SHOULDER PAIN

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐
No ☒

Start date (dd MMM yyyy)

19 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

01 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

AEID

Adverse event

DIARRHEA

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐
No ☒

Start date (dd MMM yyyy)

16 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

16 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

AEID

Adverse event

WORSENING OF LEFT KNEE
OSTEOARTHRITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAD A KNEE JOINT ASPIRATION SUDDENLY DUE TO FLUID BUILDUP FROM OSTEOARTHRITIS. TOOK A SHOT OF CORTISONE. NO ADDITIONAL MEDICATIONS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

AEID	
Adverse event	URI
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

AEID	
Adverse event	LEFT BREAST SORE
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)	27 DEC 2020
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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

AEID	
Adverse event	UTI
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)	26 JAN 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

AEID

Adverse event

FATIGUE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

06 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" 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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

AEID	
Adverse event	RIGHT HAMSTRING INJURY
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)	25 FEB 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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

AEID	USA-US062-2021-MRNA-1273-P30 1000014
Adverse event	INTERMITTENT HEMATURIA
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)	02 MAR 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)	23 APR 2021
Hospital Discharge Date (dd MMM yyyy)	24 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT SEEN ON 23APR2021 FOR OVERNIGHT STAY IN HOSPITAL DUE TO CYSTOSCOPY AND BULKING PROCEDURE FOR EXISTING AE.
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: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

AEID	USA-US062-2021-MRNA-1273-P30 1000014
Adverse event	FULL THICKNESS TEAR OF SUPRASPINATUS TENDON
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)	23 MAR 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 type="radio"/> Grade 3/Severe <input checked="" 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)	25 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	27 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT REPORTS ONSET OF PAIN ON 23MAR2021, PAIN CLIMAXED ON 25MAR2021 LEADING TO HOSPITAL VISIT. PATIENT SPEND THE NIGHT AT HOSPITAL AND IS STILL ADMITTED AT TIME OF INITIAL REPORT.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

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

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

AEID	
Adverse event	LEFT OVARIAN CYST
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)	14 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

AEID	
Adverse event	HYPERTENSION
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)	23 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication DESMOPRESSIN

Prophylaxis Yes ☐
No ☒

Indication OVERACTIVE BLADDER

Dose per administration 1

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) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN

Dose per administration 900

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) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	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 (3)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	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)	2	
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 (4)

Data signed: (b) (4) 08 Apr 2021 22:48:31

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Name of Medication LYRICA

Prophylaxis Yes ☐
No ☒

Indication NEURALGIA/CHRONIC PAIN

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 (4)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	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 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication COLACE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

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 (5)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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 (6)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication FLUNISOLIDE NASAL SOLUTION

Prophylaxis Yes ☐
No ☒

Indication ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify SPRAY

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication LINZESS

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

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 (7)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
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 (8)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 90

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

If dose unit is Other, specify MCG/INHALATION

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) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1978	
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 (9)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication VOLTAREN TOPICAL GEL 1%

Prophylaxis Yes ☐
No ☒

Indication RIGHT SHOULDER PAIN

Dose per administration 1

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

If dose unit is Other, specify LAYER

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 (9)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	01 SEP 2020	
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 (10)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT SHOULDER PAIN

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 (10)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	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)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 01 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication HCTZ

Prophylaxis Yes ☐
No ☒

Indication LEFT KNEE EDEMA

Dose per administration 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 (11)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (12)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication PEPTO BISMO

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 15

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 (12)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 17 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication CORTISONE SHOT

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS/KNEE JOINT
ASPIRATION

Dose per administration 1

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

If dose unit is Other, specify SHOT

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 22:48:31

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRA-ARTICULAR	
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication MUPIROCIN

Prophylaxis Yes ☐
No ☒

Indication LEFT BREAST SORE

Dose per administration 2

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 (14)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	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)	27 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
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 (15)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication MACROBID

Prophylaxis Yes ☐
No ☒

Indication UTI

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 (15)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication R HAMSTRING INJURY

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 (16)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	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)	25 FEB 2021	
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"/>

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication MACROBID

Prophylaxis Yes ☐
No ☒

Indication UTI

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 (17)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 FEB 2021
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 (18)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication FULL THICKNESS TEAR OF
SUPRASPINATUS TENDON

Dose per administration 10-325

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	27 MAR 2021	
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 (19)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication KEFLEX

Prophylaxis Yes ☐
No ☒

Indication RECURRENT UTI'S

Dose per administration 250

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 (19)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	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)	28 MAR 2021	
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 (20)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication GI PROPHYLAXIS

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 (20)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 MAR 2021	
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 (21)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication ROBAXIN

Prophylaxis Yes ☐
No ☒

Indication RIGHT HAMSTRING INJURY

Dose per administration 750

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 (21)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 MAR 2021	
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)	3	
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 (22)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication FULL THICKNESS TEAR OF
SUPRASPINATUS TENDON

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

Q12HRS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	27 MAR 2021	
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 (23)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication FULL THICKNESS TEAR OF
SUPRASPINATUS TENDON

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 MAR 2021	
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 (24)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION SECONDARY
TO HOSPITAL MEDICATIONS
(FULL THICKNESS TEAR OF
SUPRASPINATUS TENDON)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 MAR 2021	
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="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

490 of 3340

EAB) (1725)

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	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)	27 MAR 2021	
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"/>

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

Name of Medication MIRALAX PACKET 17 GM

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION SECONDARY
TO HOSPITAL MEDICATIONS
(FULL THICKNESS TEAR OF
SUPRASPINATUS TENDON)

Dose per administration 1

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

If dose unit is Other, specify PACKET

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

492 of 3340

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 08 Apr 2021 22:48:31

Generated On: 09 Jun 2021 15:09:10

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 MAR 2021	
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"/>

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:59:04

Generated On: 09 Jun 2021 15:09:10

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 30 Apr 2021 17:54:57

Generated On: 09 Jun 2021 15:09:10

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 NOV 2020	KNEE JOINT ASPIRATION	Adverse Event	
23 APR 2021	CYSTOSCOPY AND BULKING	Adverse Event	

US3112113

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:09:10

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

US3112113

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:09:10

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 ☐

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 19:04:39

Generated On: 09 Jun 2021 15:09:10

SAEID	USA-US062-2021-MRNA-1273-P301000014
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 19:04:39

Generated On: 09 Jun 2021 15:09:10

SAEID	USA-US062-2021-MRNA-1273-P301000014
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/MAR/2021 12:01
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

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 19:04:39

Generated On: 09 Jun 2021 15:09:10

SAEID	USA-US062-2021-MRNA-1273-P301000014
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/APR/2021 12:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 19:04:39

Generated On: 09 Jun 2021 15:09:10

SAEID	USA-US062-2021-MRNA-1273-P301000014
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/APR/2021 06:17
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

US3112113 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112113

Form: Participant Creation

Generated On: 09 Jun 2021 15:09:10

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'US3112113'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:29:14

US3112113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	05 Aug 2020 22:03:57

US3112113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:29:15

US3112113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Clinic (Clinic)'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 22:03:57

US3112113

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'SCRN'	System	05 Aug 2020 22:03:57

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:29:16

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '61'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'YEARS'	System	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '61'	System	05 Aug 2020 22:04:06

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Female (F)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'I'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:10

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:41

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '5 Aug 2020'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 22:04:06

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Aug 2020'	System	05 Aug 2020 22:04:06

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2020'	System	05 Aug 2020 22:04:06

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Amendment 1 (1)'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 22:04:06

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 22:04:06

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	(b) (4) Matthew Musikanth	05 Aug 2020 22:04:06
	(b) (4)	

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	(b) (4) Matthew Musikanth	05 Aug 2020 22:04:06
	(b) (4)	

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	(b) (4) Matthew Musikanth	05 Aug 2020 22:04:06
	(b) (4)	

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 20:29:15

US3112113

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:10

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'I'	System	05 Aug 2020 22:04:12

US3112113

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:09:10

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	05 Aug 2020 22:04:12

US3112113

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:09:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:23:11
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'Med HX update' (Site from DM).	Karen Mylerberg (b) (4)	05 Sep 2020 17:43:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 17:43:46
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:55:45
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:33:49

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:45:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:45:38
Data point term sent to Coder	System	05 Sep 2020 17:45:00
User entered 'Seasonal allergies'	Karen Mylerberg (b) (4)	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 1978'	Karen Mylerberg (b) (4)	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 1978'	System	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '1978'	System	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:44:47

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:46:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:46:39
Data point term sent to Coder	System	05 Sep 2020 17:46:02
User entered 'Overactive Bladder'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 2017'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2017'	System	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2017'	System	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:45:11

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:46:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:46:39
Data point term sent to Coder	System	05 Sep 2020 17:46:02
User entered 'Left knee osteoarthritis'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 2010'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2010'	System	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2010'	System	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:45:32

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:48:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:48:39
Data point term sent to Coder	System	05 Sep 2020 17:47:02
User entered 'Right knee osteoarthritis'	Karen Mylerberg (b) (4)	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 2010'	Karen Mylerberg (b) (4)	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 2016'	Karen Mylerberg (b) (4)	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2010'	System	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2010'	System	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2016'	System	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2016'	System	05 Sep 2020 17:46:41

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:48:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:48:39
Data point term sent to Coder	System	05 Sep 2020 17:48:04
User entered 'Total right knee replacement'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'un UNK 2016'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 2016'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2016'	System	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2016'	System	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2016'	System	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2016'	System	05 Sep 2020 17:47:17

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 05:43:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 05:43:45
Data point term sent to Coder	System	05 Sep 2020 17:48:03
User entered 'Left chronic knee pain'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 2010'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2010'	System	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2010'	System	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:47:45

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:49:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:49:40
Data point term sent to Coder	System	05 Sep 2020 17:49:06
User entered 'Asthma'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 1978'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 1978'	System	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '1978'	System	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:48:27

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:49:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:49:39
Data point term sent to Coder	System	05 Sep 2020 17:49:04
User entered 'Sleep apnea'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN Jun 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jun 2020'	System	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2020'	System	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:48:58

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:50:40
Data point term sent to Coder	System	05 Sep 2020 17:50:07
User entered 'Bilateral lower extremity edema'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'un Jul 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jul 2020'	System	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2020'	System	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:49:35

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:50:40
Data point term sent to Coder	System	05 Sep 2020 17:50:07
User entered 'Constipation'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2015'	System	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2015'	System	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:49:51

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Neuralgia, LLT: Neuralgia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:51:40
Data point term sent to Coder	System	05 Sep 2020 17:51:07
User entered 'Neuralgia'	Karen Mylerberg (b) (4)	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4)	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2015'	System	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2015'	System	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	05 Sep 2020 17:50:15

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 00:52:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 00:52:00
Data point term sent to Coder	System	03 Dec 2020 00:50:30
User entered 'cholelithiasis'	Karen Mylerberg (b) (4)	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 1990'	Karen Mylerberg (b) (4)	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 1990'	Karen Mylerberg (b) (4)	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 1990'	System	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '1990'	System	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 1990'	System	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '1990'	System	03 Dec 2020 00:49:45

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 00:53:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 00:53:01
Data point term sent to Coder	System	03 Dec 2020 00:51:30
User entered 'cholecystectomy'	Karen Mylerberg (b) (4)	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 1990'	Karen Mylerberg (b) (4)	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'UN UNK 1990'	Karen Mylerberg (b) (4)	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 1990'	System	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '1990'	System	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 1990'	System	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '1990'	System	03 Dec 2020 00:50:56

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg cramps - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 00:07:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 00:07:01
Data point term sent to Coder	System	01 Mar 2021 16:33:37
User entered 'Bilateral Leg Cramping'	Matthew Musikanth (b) (4)	01 Mar 2021 16:33:31

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered 'un Jan 2020'	(b) (4) Matthew Musikanth (b) (4)	01 Mar 2021 16:33:31

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	01 Mar 2021 16:33:31

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	01 Mar 2021 16:33:31

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered empty.	(b) (4) Matthew Musikanth	01 Mar 2021 16:33:31
	(b) (4)	

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered '0'	(b) (4) Matthew Musikanth	01 Mar 2021 16:33:31

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'Jan 2020'	System	01 Mar 2021 16:33:31

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '2020'	System	01 Mar 2021 16:33:31

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	01 Mar 2021 16:33:31

US3112113

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:09:10

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered empty.	System	01 Mar 2021 16:33:31

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '12:55'	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered '5 Aug 2020 12:55'	System	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '67' in	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53
DataPoint set to visible.	System	05 Aug 2020 22:04:12

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '326' lb	(b) (4) Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53
DataPoint set to visible.	(b) (4) System	05 Aug 2020 22:04:12

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
Amendment Manager: User entered '51.16558'	System	16 Sep 2020 23:44:37
User entered '51.2'	System	13 Aug 2020 14:34:53
DataPoint set to visible.	System	05 Aug 2020 22:04:12

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'kg/m2'	System	13 Aug 2020 14:34:53
DataPoint set to visible.	System	05 Aug 2020 22:04:12

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 03:43:53
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Updated ' (Site from DM).	Karen Mylerberg (b) (4)	05 Sep 2020 04:00:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 03:59:54
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:59:50
User entered '97.6' F	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty; reason for change Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	05 Sep 2020 03:59:54
User entered 'Oral (Oral)'	(b) (4)	
	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53
	(b) (4)	

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 03:59:54
User entered '80'	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'bpm'	System	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 03:59:54
User entered '18'	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'breaths/min'	System	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 03:59:54
User entered '139'	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'mmHg'	System	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 03:59:54
User entered '076'	Karen Mylerberg (b) (4)	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User entered 'mmHg'	System	13 Aug 2020 14:34:53

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41

US3112113

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41

US3112113

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:35:52

US3112113

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:48:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 20:53:30
User entered '5 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	13 Aug 2020 14:35:52

US3112113

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:12

US3112113

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:10

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:12

US3112113

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:10

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:12

US3112113

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:10

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:12

US3112113

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:10

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:12

US3112113

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:10

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:12

US3112113

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:10

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:12

US3112113

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:10

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'I'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:12

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[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

Form: Risk of Exposure

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Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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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)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:10

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:10

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:10

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:10

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered 'I'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:10

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered '0'	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

US3112113

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:56:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:45:01
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:36:48

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:37:03

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 14:37:03

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:37:03

US3112113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'VISIT1'	System	13 Aug 2020 14:37:03

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 21:14:15

US3112113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:10

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:21:49
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:21:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 21:14:15
User entered '142922' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 21:14:15

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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 21:14:15

US3112113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:10

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:37:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:10

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:37:18

US3112113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:10

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:37:18

US3112113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:10

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:37:18

US3112113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:37:18

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '12:55'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '5 Aug 2020 12:55'	System	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '97.6' F	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '80'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'bpm'	System	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '18'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'breaths/min'	System	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '139'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'mmHg'	System	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '076'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'mmHg'	System	13 Aug 2020 14:39:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:10

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4)	18 Aug 2020 16:01:03
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 14:39:20
User entered '15:32'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20
	(b) (4)	

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '5 Aug 2020 15:32'	System	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '97.7' F	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '90'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'bpm'	System	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '18'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'breaths/min'	System	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '152'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'mmHg'	System	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '092'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'mmHg'	System	13 Aug 2020 14:39:20

US3112113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:34

US3112113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 14:39:34

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	05 Aug 2020 22:04:33
	(b) (4)	

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	(b) (4) Matthew Musikanth	05 Aug 2020 22:04:33
	(b) (4)	

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	Matthew Musikanth (b) (4)	05 Aug 2020 22:04:33

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 22:04:33

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '5 Aug 2020'	(b) (4) Matthew Musikanth	05 Aug 2020 22:04:33
	(b) (4)	

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '14:58'	(b) (4) Matthew Musikanth	05 Aug 2020 22:04:33
	(b) (4)	

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '5 Aug 2020 14:58'	System	05 Aug 2020 22:04:33

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	05 Aug 2020 22:04:33

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'ONCE'	System	05 Aug 2020 22:04:33

US3112113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 22:04:33

US3112113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:27

US3112113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:27

US3112113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '14:18'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:27

US3112113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '5 Aug 2020 14:18'	System	13 Aug 2020 14:42:27

US3112113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:09:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '5 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:44

US3112113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:44

US3112113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:44

US3112113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '13:59'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:44

US3112113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '5 Aug 2020 13:59'	System	13 Aug 2020 14:42:44

US3112113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:44

US3112113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'No (N)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:44

US3112113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:44

US3112113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered empty.	System	13 Aug 2020 14:42:44

US3112113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:42:51

US3112113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'I'	System	13 Aug 2020 14:42:51

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:34:51', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd933da72-1f5f-4ea2-aca4-e72124f78d88'	System	05 Aug 2020 22:35:37
User entered 'Yes (Y)'	System	05 Aug 2020 22:35:37

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:34:58', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd933da72-1f5f-4ea2-aca4-e72124f78d88'	System	05 Aug 2020 22:35:37
User entered '97.7'	System	05 Aug 2020 22:35:37

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:35:08', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd933da72-1f5f-4ea2-aca4-e72124f78d88'	System	05 Aug 2020 22:35:37
User entered 'Yes (Y)'	System	05 Aug 2020 22:35:37

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:35:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd933da72-1f5f-4ea2-aca4-e72124f78d88'	System	05 Aug 2020 22:35:37
User entered '0'	System	05 Aug 2020 22:35:37

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contacted doesn't remember' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 12:41:11
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Natalie Moy (b) (4)	15 Oct 2020 20:28:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:35:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd933da72-1f5f-4ea2-aca4-e72124f78d88'	System	05 Aug 2020 22:35:37
User entered '1'	System	05 Aug 2020 22:35:37

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:35:33', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd933da72-1f5f-4ea2-aca4-e72124f78d88'	System	05 Aug 2020 22:35:37
User entered '05 Aug 2020 15:35'	System	05 Aug 2020 22:35:37

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Aug 2020 15:18'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Aug 2020 17:48'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:09:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e5d57011-3b1b-473a-a5d0-23cde982c96e'	System	06 Aug 2020 05:09:40
User entered 'Yes (Y)'	System	06 Aug 2020 05:09:40

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:09:18', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e5d57011-3b1b-473a-a5d0-23cde982c96e' User entered '98.6'	System	06 Aug 2020 05:09:40
	System	06 Aug 2020 05:09:40

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:09:26', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e5d57011-3b1b-473a-a5d0-23cde982c96e'	System	06 Aug 2020 05:09:40
User entered 'No (N)'	System	06 Aug 2020 05:09:40

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:09:38', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e5d57011-3b1b-473a-a5d0-23cde982c96e'	System	06 Aug 2020 05:09:40
User entered '05 Aug 2020 22:09'	System	06 Aug 2020 05:09:40

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Aug 2020 18:43'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 2'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T11:46:01', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b1292e10-5f44-492d-94d4-f3674875e6c0'	System	07 Aug 2020 18:46:17
User entered 'Yes (Y)'	System	07 Aug 2020 18:46:17

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T11:46:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b1292e10-5f44-492d-94d4-f3674875e6c0'	System	07 Aug 2020 18:46:17
User entered '97.5'	System	07 Aug 2020 18:46:17

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T11:46:11', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b1292e10-5f44-492d-94d4-f3674875e6c0'	System	07 Aug 2020 18:46:17
User entered 'No (N)'	System	07 Aug 2020 18:46:17

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T11:46:14', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b1292e10-5f44-492d-94d4-f3674875e6c0'	System	07 Aug 2020 18:46:17
User entered '07 Aug 2020 11:46'	System	07 Aug 2020 18:46:17

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 3'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:22:48', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc76a0a0-8136-441f-9341-9032e0a40ca1'	System	08 Aug 2020 05:23:09
User entered 'Yes (Y)'	System	08 Aug 2020 05:23:09

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:22:58', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc76a0a0-8136-441f-9341-9032e0a40ca1'	System	08 Aug 2020 05:23:09
User entered '98.3'	System	08 Aug 2020 05:23:09

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:23:01', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc76a0a0-8136-441f-9341-9032e0a40ca1'	System	08 Aug 2020 05:23:09
User entered 'No (N)'	System	08 Aug 2020 05:23:09

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:23:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc76a0a0-8136-441f-9341-9032e0a40ca1'	System	08 Aug 2020 05:23:09
User entered '07 Aug 2020 22:23'	System	08 Aug 2020 05:23:09

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 4'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:54:04', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '330171c4-79b1-4813-97e6-1f8654f2b4f0'	System	09 Aug 2020 05:54:35
User entered 'Yes (Y)'	System	09 Aug 2020 05:54:35

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:54:21', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '330171c4-79b1-4813-97e6-1f8654f2b4f0'	System	09 Aug 2020 05:54:35
User entered '99.0'	System	09 Aug 2020 05:54:35

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:54:26', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '330171c4-79b1-4813-97e6-1f8654f2b4f0'	System	09 Aug 2020 05:54:35
User entered 'No (N)'	System	09 Aug 2020 05:54:35

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:54:31', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '330171c4-79b1-4813-97e6-1f8654f2b4f0'	System	09 Aug 2020 05:54:35
User entered '08 Aug 2020 22:54'	System	09 Aug 2020 05:54:35

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 5'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:26:35', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b104403a-513f-41a6-b568-0fecfd57629d'	System	10 Aug 2020 01:26:57
User entered 'Yes (Y)'	System	10 Aug 2020 01:26:57

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:26:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b104403a-513f-41a6-b568-0fecfd57629d'	System	10 Aug 2020 01:26:57
User entered '97.9'	System	10 Aug 2020 01:26:57

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:26:48', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b104403a-513f-41a6-b568-0fecfd57629d'	System	10 Aug 2020 01:26:57
User entered 'No (N)'	System	10 Aug 2020 01:26:57

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:26:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b104403a-513f-41a6-b568-0fecfd57629d'	System	10 Aug 2020 01:26:57
User entered '09 Aug 2020 18:26'	System	10 Aug 2020 01:26:57

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 6'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:11:38', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '577aee64-d33e-49b5-b404-314c87c89d0c'	System	11 Aug 2020 18:12:49
User entered 'Yes (Y)'	System	11 Aug 2020 18:12:49

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:12:38', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '577aee64-d33e-49b5-b404-314c87c89d0c' User entered '97.1'	System	11 Aug 2020 18:12:49
	System	11 Aug 2020 18:12:49

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:12:42', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '577aee64-d33e-49b5-b404-314c87c89d0c'	System	11 Aug 2020 18:12:49
User entered 'No (N)'	System	11 Aug 2020 18:12:49

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:12:45', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '577aee64-d33e-49b5-b404-314c87c89d0c'	System	11 Aug 2020 18:12:49
User entered '11 Aug 2020 11:12'	System	11 Aug 2020 18:12:49

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 7'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:58:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bfe8e031-af3b-4726-a58d-f8b67347c872'	System	12 Aug 2020 02:59:05
User entered 'Yes (Y)'	System	12 Aug 2020 02:59:05

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:58:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bfe8e031-af3b-4726-a58d-f8b67347c872'	System	12 Aug 2020 02:59:05
User entered '97.6'	System	12 Aug 2020 02:59:05

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:58:57', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bfe8e031-af3b-4726-a58d-f8b67347c872'	System	12 Aug 2020 02:59:05
User entered 'No (N)'	System	12 Aug 2020 02:59:05

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:01', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bfe8e031-af3b-4726-a58d-f8b67347c872'	System	12 Aug 2020 02:59:05
User entered '11 Aug 2020 19:59'	System	12 Aug 2020 02:59:05

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:35:58', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dc094c35-725f-47db-ba73-3066c2899f68'	System	05 Aug 2020 22:36:34
User entered 'None (1)'	System	05 Aug 2020 22:36:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:36:02', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dc094c35-725f-47db-ba73-3066c2899f68'	System	05 Aug 2020 22:36:34
User entered 'No (N)'	System	05 Aug 2020 22:36:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:36:08', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dc094c35-725f-47db-ba73-3066c2899f68'	System	05 Aug 2020 22:36:34
User entered 'No (N)'	System	05 Aug 2020 22:36:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:36:25', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dc094c35-725f-47db-ba73-3066c2899f68'	System	05 Aug 2020 22:36:34
User entered 'None (1)'	System	05 Aug 2020 22:36:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:36:31', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dc094c35-725f-47db-ba73-3066c2899f68'	System	05 Aug 2020 22:36:34
User entered '05 Aug 2020 15:36'	System	05 Aug 2020 22:36:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Aug 2020 15:18'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Aug 2020 17:48'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:09:49', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a3a46c2e-fb77-4665-86a7-dc8d66c06621'	System	06 Aug 2020 05:13:17
User entered 'None (1)'	System	06 Aug 2020 05:13:17

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:09:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a3a46c2e-fb77-4665-86a7-dc8d66c06621'	System	06 Aug 2020 05:13:17
User entered 'No (N)'	System	06 Aug 2020 05:13:17

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:12:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a3a46c2e-fb77-4665-86a7-dc8d66c06621'	System	06 Aug 2020 05:13:17
User entered 'Yes (Y)'	System	06 Aug 2020 05:13:17

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:12:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a3a46c2e-fb77-4665-86a7-dc8d66c06621'	System	06 Aug 2020 05:13:17
User entered '3'	System	06 Aug 2020 05:13:17

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:05', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a3a46c2e-fb77-4665-86a7-dc8d66c06621'	System	06 Aug 2020 05:13:17
User entered 'None (1)'	System	06 Aug 2020 05:13:17

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:11', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a3a46c2e-fb77-4665-86a7-dc8d66c06621'	System	06 Aug 2020 05:13:17
User entered '05 Aug 2020 22:13'	System	06 Aug 2020 05:13:17

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Aug 2020 18:43'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 2'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:50:15', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '735578ac-08a2-4ce0-8504-db654dfa8b4a'	System	07 Aug 2020 16:50:54
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 16:50:54

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:50:19', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '735578ac-08a2-4ce0-8504-db654dfa8b4a'	System	07 Aug 2020 16:50:54
User entered 'No (N)'	System	07 Aug 2020 16:50:54

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:50:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '735578ac-08a2-4ce0-8504-db654dfa8b4a'	System	07 Aug 2020 16:50:54
User entered 'No (N)'	System	07 Aug 2020 16:50:54

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:50:43', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '735578ac-08a2-4ce0-8504-db654dfa8b4a'	System	07 Aug 2020 16:50:54
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 16:50:54

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:50:51', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '735578ac-08a2-4ce0-8504-db654dfa8b4a'	System	07 Aug 2020 16:50:54
User entered '07 Aug 2020 09:50'	System	07 Aug 2020 16:50:54

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 3'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:23:15', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e52767b6-3171-4794-bdc3-807e195006d3'	System	08 Aug 2020 05:23:47
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 05:23:47

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:23:19', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e52767b6-3171-4794-bdc3-807e195006d3'	System	08 Aug 2020 05:23:47
User entered 'No (N)'	System	08 Aug 2020 05:23:47

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:23:36', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e52767b6-3171-4794-bdc3-807e195006d3'	System	08 Aug 2020 05:23:47
User entered 'No (N)'	System	08 Aug 2020 05:23:47

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:23:42', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e52767b6-3171-4794-bdc3-807e195006d3'	System	08 Aug 2020 05:23:47
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 05:23:47

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:23:45', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e52767b6-3171-4794-bdc3-807e195006d3'	System	08 Aug 2020 05:23:47
User entered '07 Aug 2020 22:23'	System	08 Aug 2020 05:23:47

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 4'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:54:40', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '5dc88011-4f6a-4d75-a644-92e57a62173b'	System	09 Aug 2020 05:55:02
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 05:55:02

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:54:43', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '5dc88011-4f6a-4d75-a644-92e57a62173b'	System	09 Aug 2020 05:55:02
User entered 'No (N)'	System	09 Aug 2020 05:55:02

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:54:49', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '5dc88011-4f6a-4d75-a644-92e57a62173b'	System	09 Aug 2020 05:55:02
User entered 'No (N)'	System	09 Aug 2020 05:55:02

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:54:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '5dc88011-4f6a-4d75-a644-92e57a62173b'	System	09 Aug 2020 05:55:02
User entered 'None (1)'	System	09 Aug 2020 05:55:02

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:54:59', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '5dc88011-4f6a-4d75-a644-92e57a62173b'	System	09 Aug 2020 05:55:02
User entered '08 Aug 2020 22:54'	System	09 Aug 2020 05:55:02

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 5'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:27:03', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bfe7f191-dcdd-4dac-b307-b24451a34fbf'	System	10 Aug 2020 01:27:36
User entered 'None (1)'	System	10 Aug 2020 01:27:36

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:27:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bfe7f191-dcdd-4dac-b307-b24451a34fbf'	System	10 Aug 2020 01:27:36
User entered 'No (N)'	System	10 Aug 2020 01:27:36

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:27:12', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bfe7f191-dcdd-4dac-b307-b24451a34fbf'	System	10 Aug 2020 01:27:36
User entered 'No (N)'	System	10 Aug 2020 01:27:36

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:27:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bfe7f191-dcdd-4dac-b307-b24451a34fbf'	System	10 Aug 2020 01:27:36
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 01:27:36

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:27:35', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bfe7f191-dcdd-4dac-b307-b24451a34fbf'	System	10 Aug 2020 01:27:36
User entered '09 Aug 2020 18:27'	System	10 Aug 2020 01:27:36

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 6'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:12:51', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '829091f8-57e2-4d12-9c7b-1489dcdac340'	System	11 Aug 2020 18:13:07
User entered 'None (1)'	System	11 Aug 2020 18:13:07

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:12:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '829091f8-57e2-4d12-9c7b-1489dcdac340'	System	11 Aug 2020 18:13:07
User entered 'No (N)'	System	11 Aug 2020 18:13:07

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:12:56', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '829091f8-57e2-4d12-9c7b-1489dcdac340'	System	11 Aug 2020 18:13:07
User entered 'No (N)'	System	11 Aug 2020 18:13:07

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:12:58', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '829091f8-57e2-4d12-9c7b-1489dcdac340'	System	11 Aug 2020 18:13:07
User entered 'None (1)'	System	11 Aug 2020 18:13:07

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:13:03', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '829091f8-57e2-4d12-9c7b-1489dcdac340'	System	11 Aug 2020 18:13:07
User entered '11 Aug 2020 11:13'	System	11 Aug 2020 18:13:07

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 7'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '384dc67d-00b3-483f-8f3e-26bb8212df14'	System	12 Aug 2020 02:59:34
User entered 'None (1)'	System	12 Aug 2020 02:59:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:10', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '384dc67d-00b3-483f-8f3e-26bb8212df14'	System	12 Aug 2020 02:59:34
User entered 'No (N)'	System	12 Aug 2020 02:59:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:13', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '384dc67d-00b3-483f-8f3e-26bb8212df14'	System	12 Aug 2020 02:59:34
User entered 'No (N)'	System	12 Aug 2020 02:59:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:20', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '384dc67d-00b3-483f-8f3e-26bb8212df14'	System	12 Aug 2020 02:59:34
User entered 'None (1)'	System	12 Aug 2020 02:59:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '384dc67d-00b3-483f-8f3e-26bb8212df14'	System	12 Aug 2020 02:59:34
User entered '11 Aug 2020 19:59'	System	12 Aug 2020 02:59:34

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:36:46', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9b46eded-14d4-41ef-a9af-762d5ffabe91'	System	05 Aug 2020 22:37:39
User entered 'None (0)'	System	05 Aug 2020 22:37:39

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:36:52', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9b46eded-14d4-41ef-a9af-762d5ffabe91'	System	05 Aug 2020 22:37:39
User entered 'None (0)'	System	05 Aug 2020 22:37:39

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:36:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9b46eded-14d4-41ef-a9af-762d5ffabe91'	System	05 Aug 2020 22:37:39
User entered 'None (0)'	System	05 Aug 2020 22:37:39

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:37:21', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9b46eded-14d4-41ef-a9af-762d5ffabe91'	System	05 Aug 2020 22:37:39
User entered 'None (0)'	System	05 Aug 2020 22:37:39

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:37:26', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9b46eded-14d4-41ef-a9af-762d5ffabe91'	System	05 Aug 2020 22:37:39
User entered 'None (0)'	System	05 Aug 2020 22:37:39

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:37:29', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9b46eded-14d4-41ef-a9af-762d5ffabe91'	System	05 Aug 2020 22:37:39
User entered 'None (0)'	System	05 Aug 2020 22:37:39

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:37:33', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9b46eded-14d4-41ef-a9af-762d5ffabe91'	System	05 Aug 2020 22:37:39
User entered 'No (N)'	System	05 Aug 2020 22:37:39

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T15:37:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9b46eded-14d4-41ef-a9af-762d5ffabe91'	System	05 Aug 2020 22:37:39
User entered '05 Aug 2020 15:37'	System	05 Aug 2020 22:37:39

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Aug 2020 15:18'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Aug 2020 17:48'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:19', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dcf28f8d-312f-4b46-8ca3-6ffd712ef888'	System	06 Aug 2020 05:13:52
User entered 'None (0)'	System	06 Aug 2020 05:13:52

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:22', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dcf28f8d-312f-4b46-8ca3-6ffd712ef888'	System	06 Aug 2020 05:13:52
User entered 'None (0)'	System	06 Aug 2020 05:13:52

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:25', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dcf28f8d-312f-4b46-8ca3-6ffd712ef888'	System	06 Aug 2020 05:13:52
User entered 'None (0)'	System	06 Aug 2020 05:13:52

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:29', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dcf28f8d-312f-4b46-8ca3-6ffd712ef888'	System	06 Aug 2020 05:13:52
User entered 'None (0)'	System	06 Aug 2020 05:13:52

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:32', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dcf28f8d-312f-4b46-8ca3-6ffd712ef888'	System	06 Aug 2020 05:13:52
User entered 'None (0)'	System	06 Aug 2020 05:13:52

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:35', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dcf28f8d-312f-4b46-8ca3-6ffd712ef888'	System	06 Aug 2020 05:13:52
User entered 'None (0)'	System	06 Aug 2020 05:13:52

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dcf28f8d-312f-4b46-8ca3-6ffd712ef888'	System	06 Aug 2020 05:13:52
User entered 'No (N)'	System	06 Aug 2020 05:13:52

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-05T22:13:50', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'dcf28f8d-312f-4b46-8ca3-6ffd712ef888'	System	06 Aug 2020 05:13:52
User entered '05 Aug 2020 22:13'	System	06 Aug 2020 05:13:52

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Aug 2020 18:43'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 2'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:51:14', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9e520aa-a7cf-4db7-9a4b-66d12e1cedc9'	System	07 Aug 2020 16:52:34
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Aug 2020 16:52:34

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:51:22', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9e520aa-a7cf-4db7-9a4b-66d12e1cedc9'	System	07 Aug 2020 16:52:34
User entered 'Some interference with activity (2)'	System	07 Aug 2020 16:52:34

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:51:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9e520aa-a7cf-4db7-9a4b-66d12e1cedc9'	System	07 Aug 2020 16:52:34
User entered 'No interference with activity (1)'	System	07 Aug 2020 16:52:34

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:51:46', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9e520aa-a7cf-4db7-9a4b-66d12e1cedc9'	System	07 Aug 2020 16:52:34
User entered 'None (0)'	System	07 Aug 2020 16:52:34

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:51:51', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9e520aa-a7cf-4db7-9a4b-66d12e1cedc9'	System	07 Aug 2020 16:52:34
User entered 'None (0)'	System	07 Aug 2020 16:52:34

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:52:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9e520aa-a7cf-4db7-9a4b-66d12e1cedc9'	System	07 Aug 2020 16:52:34
User entered 'None (0)'	System	07 Aug 2020 16:52:34

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:52:23', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9e520aa-a7cf-4db7-9a4b-66d12e1cedc9'	System	07 Aug 2020 16:52:34
User entered 'Yes (Y)'	System	07 Aug 2020 16:52:34

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T09:52:30', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9e520aa-a7cf-4db7-9a4b-66d12e1cedc9'	System	07 Aug 2020 16:52:34
User entered '07 Aug 2020 09:52'	System	07 Aug 2020 16:52:34

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 3'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:23:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '28b55a73-db04-42e5-94a3-d241f5d6c140'	System	08 Aug 2020 05:24:21
User entered 'No interference with activity (1)'	System	08 Aug 2020 05:24:21

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:23:59', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '28b55a73-db04-42e5-94a3-d241f5d6c140'	System	08 Aug 2020 05:24:21
User entered 'Some interference with activity (2)'	System	08 Aug 2020 05:24:21

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:24:03', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '28b55a73-db04-42e5-94a3-d241f5d6c140'	System	08 Aug 2020 05:24:21
User entered 'No interference with activity (1)'	System	08 Aug 2020 05:24:21

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:24:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '28b55a73-db04-42e5-94a3-d241f5d6c140'	System	08 Aug 2020 05:24:21
User entered 'None (0)'	System	08 Aug 2020 05:24:21

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:24:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '28b55a73-db04-42e5-94a3-d241f5d6c140'	System	08 Aug 2020 05:24:21
User entered 'None (0)'	System	08 Aug 2020 05:24:21

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:24:11', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '28b55a73-db04-42e5-94a3-d241f5d6c140'	System	08 Aug 2020 05:24:21
User entered 'None (0)'	System	08 Aug 2020 05:24:21

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:24:15', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '28b55a73-db04-42e5-94a3-d241f5d6c140'	System	08 Aug 2020 05:24:21
User entered 'No (N)'	System	08 Aug 2020 05:24:21

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-07T22:24:18', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '28b55a73-db04-42e5-94a3-d241f5d6c140'	System	08 Aug 2020 05:24:21
User entered '07 Aug 2020 22:24'	System	08 Aug 2020 05:24:21

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 4'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:55:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '75594e88-e668-4875-97a9-07a861c90c67'	System	09 Aug 2020 05:55:38
User entered 'None (0)'	System	09 Aug 2020 05:55:38

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:55:10', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '75594e88-e668-4875-97a9-07a861c90c67'	System	09 Aug 2020 05:55:38
User entered 'Some interference with activity (2)'	System	09 Aug 2020 05:55:38

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:55:15', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '75594e88-e668-4875-97a9-07a861c90c67'	System	09 Aug 2020 05:55:38
User entered 'No interference with activity (1)'	System	09 Aug 2020 05:55:38

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:55:18', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '75594e88-e668-4875-97a9-07a861c90c67'	System	09 Aug 2020 05:55:38
User entered 'None (0)'	System	09 Aug 2020 05:55:38

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:55:21', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '75594e88-e668-4875-97a9-07a861c90c67'	System	09 Aug 2020 05:55:38
User entered 'None (0)'	System	09 Aug 2020 05:55:38

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:55:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '75594e88-e668-4875-97a9-07a861c90c67'	System	09 Aug 2020 05:55:38
User entered 'None (0)'	System	09 Aug 2020 05:55:38

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:55:31', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '75594e88-e668-4875-97a9-07a861c90c67'	System	09 Aug 2020 05:55:38
User entered 'No (N)'	System	09 Aug 2020 05:55:38

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-08T22:55:35', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '75594e88-e668-4875-97a9-07a861c90c67'	System	09 Aug 2020 05:55:38
User entered '08 Aug 2020 22:55'	System	09 Aug 2020 05:55:38

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 5'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:27:43', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '85c5af88-f622-4fa1-b4f0-5c164f3884ef'	System	10 Aug 2020 01:28:20
User entered 'None (0)'	System	10 Aug 2020 01:28:20

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:27:50', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '85c5af88-f622-4fa1-b4f0-5c164f3884ef'	System	10 Aug 2020 01:28:20
User entered 'Some interference with activity (2)'	System	10 Aug 2020 01:28:20

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:27:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '85c5af88-f622-4fa1-b4f0-5c164f3884ef'	System	10 Aug 2020 01:28:20
User entered 'No interference with activity (1)'	System	10 Aug 2020 01:28:20

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:27:59', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '85c5af88-f622-4fa1-b4f0-5c164f3884ef'	System	10 Aug 2020 01:28:20
User entered 'None (0)'	System	10 Aug 2020 01:28:20

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:28:04', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '85c5af88-f622-4fa1-b4f0-5c164f3884ef' User entered 'None (0)'	System	10 Aug 2020 01:28:20
	System	10 Aug 2020 01:28:20

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:28:08', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '85c5af88-f622-4fa1-b4f0-5c164f3884ef'	System	10 Aug 2020 01:28:20
User entered 'None (0)'	System	10 Aug 2020 01:28:20

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:28:14', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '85c5af88-f622-4fa1-b4f0-5c164f3884ef'	System	10 Aug 2020 01:28:20
User entered 'No (N)'	System	10 Aug 2020 01:28:20

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4b426acc15b4ffe7)', Time: '2020-08-09T18:28:17', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '85c5af88-f622-4fa1-b4f0-5c164f3884ef'	System	10 Aug 2020 01:28:20
User entered '09 Aug 2020 18:28'	System	10 Aug 2020 01:28:20

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 6'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:13:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7e8a855f-be7c-4f8e-9f1b-b504f04873d4'	System	11 Aug 2020 18:13:47
User entered 'None (0)'	System	11 Aug 2020 18:13:47

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:13:12', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7e8a855f-be7c-4f8e-9f1b-b504f04873d4'	System	11 Aug 2020 18:13:47
User entered 'None (0)'	System	11 Aug 2020 18:13:47

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:13:15', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7e8a855f-be7c-4f8e-9f1b-b504f04873d4'	System	11 Aug 2020 18:13:47
User entered 'None (0)'	System	11 Aug 2020 18:13:47

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:13:17', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7e8a855f-be7c-4f8e-9f1b-b504f04873d4'	System	11 Aug 2020 18:13:47
User entered 'None (0)'	System	11 Aug 2020 18:13:47

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:13:20', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7e8a855f-be7c-4f8e-9f1b-b504f04873d4'	System	11 Aug 2020 18:13:47
User entered 'None (0)'	System	11 Aug 2020 18:13:47

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:13:22', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7e8a855f-be7c-4f8e-9f1b-b504f04873d4'	System	11 Aug 2020 18:13:47
User entered 'None (0)'	System	11 Aug 2020 18:13:47

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:13:26', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7e8a855f-be7c-4f8e-9f1b-b504f04873d4'	System	11 Aug 2020 18:13:47
User entered 'No (N)'	System	11 Aug 2020 18:13:47

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T11:13:42', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7e8a855f-be7c-4f8e-9f1b-b504f04873d4'	System	11 Aug 2020 18:13:47
User entered '11 Aug 2020 11:13'	System	11 Aug 2020 18:13:47

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 7'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:32', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '57babdbe-a46f-4510-9db1-0c46efe4d15f'	System	12 Aug 2020 03:00:04
User entered 'None (0)'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:40', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '57babdbe-a46f-4510-9db1-0c46efe4d15f'	System	12 Aug 2020 03:00:04
User entered 'Some interference with activity (2)'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '57babdbe-a46f-4510-9db1-0c46efe4d15f'	System	12 Aug 2020 03:00:04
User entered 'None (0)'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:46', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '57babdbe-a46f-4510-9db1-0c46efe4d15f' User entered 'None (0)'	System	12 Aug 2020 03:00:04
	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:48', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '57babdbe-a46f-4510-9db1-0c46efe4d15f' User entered 'None (0)'	System	12 Aug 2020 03:00:04
	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:51', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '57babdbe-a46f-4510-9db1-0c46efe4d15f' User entered 'None (0)'	System	12 Aug 2020 03:00:04
	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:54', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '57babdbe-a46f-4510-9db1-0c46efe4d15f'	System	12 Aug 2020 03:00:04
User entered 'No (N)'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-11T19:59:57', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '57babdbe-a46f-4510-9db1-0c46efe4d15f'	System	12 Aug 2020 03:00:04
User entered '11 Aug 2020 19:59'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	12 Aug 2020 03:00:04
User entered 'Day 8'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-12T15:51:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd2057d73-828d-4e5f-88b7-309af395e34f'	System	12 Aug 2020 22:51:16
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:51:16

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-12T15:51:12', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd2057d73-828d-4e5f-88b7-309af395e34f'	System	12 Aug 2020 22:51:16
User entered '12 Aug 2020 15:51'	System	12 Aug 2020 22:51:16

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	12 Aug 2020 03:00:04
User entered 'Day 9'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-13T22:32:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '3e2f243a-0f6a-4904-ad7b-ef62e3e9967d'	System	14 Aug 2020 05:32:31
User entered 'Some interference with activity (2)'	System	14 Aug 2020 05:32:31

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-13T22:32:28', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '3e2f243a-0f6a-4904-ad7b-ef62e3e9967d'	System	14 Aug 2020 05:32:31
User entered '13 Aug 2020 22:32'	System	14 Aug 2020 05:32:31

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	12 Aug 2020 22:51:16
User entered 'Day 10'	System	12 Aug 2020 22:51:16

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-14T12:14:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '3d3a0aca-2956-4e13-b244-f7852c318678'	System	14 Aug 2020 19:15:12
User entered 'Some interference with activity (2)'	System	14 Aug 2020 19:15:12

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-14T12:15:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '3d3a0aca-2956-4e13-b244-f7852c318678'	System	14 Aug 2020 19:15:12
User entered '14 Aug 2020 12:15'	System	14 Aug 2020 19:15:12

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 22:51:16

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 22:51:16

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	14 Aug 2020 05:32:31
User entered 'Day 11'	System	14 Aug 2020 05:32:31

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 05:32:31

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 05:32:31

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	14 Aug 2020 19:15:12
User entered 'Day 12'	System	14 Aug 2020 19:15:12

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-16T17:34:56', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '2f7fa6e6-59aa-4e83-adb0-d8a0bb4f087b'	System	17 Aug 2020 00:35:02
User entered 'No interference with activity (1)'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-16T17:34:59', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '2f7fa6e6-59aa-4e83-adb0-d8a0bb4f087b'	System	17 Aug 2020 00:35:02
User entered '16 Aug 2020 17:34'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:15:12

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:15:12

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	17 Aug 2020 00:35:02
User entered 'Day 13'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-18T10:06:14', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '73e4d44a-0c56-40f8-8c7b-f8a9a7b5ca03'	System	18 Aug 2020 17:06:20
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:06:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-18T10:06:18', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '73e4d44a-0c56-40f8-8c7b-f8a9a7b5ca03'	System	18 Aug 2020 17:06:20
User entered '18 Aug 2020 10:06'	System	18 Aug 2020 17:06:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '17 Aug 2020 12:00'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	17 Aug 2020 00:35:02
User entered 'Day 14'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-18T23:59:49', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9feb14df-d155-4ce5-8e47-b6f463dcc362'	System	19 Aug 2020 06:59:59
User entered 'No interference with activity (1)'	System	19 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-18T23:59:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9feb14df-d155-4ce5-8e47-b6f463dcc362'	System	19 Aug 2020 06:59:59
User entered '18 Aug 2020 23:59'	System	19 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	18 Aug 2020 17:06:20
User entered 'Day 15'	System	18 Aug 2020 17:06:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-19T23:59:50', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '67fada12-c5b8-4fc8-a191-ebec39600049'	System	20 Aug 2020 06:59:59
User entered 'No interference with activity (1)'	System	20 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-19T23:59:54', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '67fada12-c5b8-4fc8-a191-ebec39600049'	System	20 Aug 2020 06:59:59
User entered '19 Aug 2020 23:59'	System	20 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:06:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:06:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	19 Aug 2020 06:59:59
User entered 'Day 16'	System	19 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-20T14:02:05', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '363df6c4-7c0b-4dde-ba57-0325e7a3a008'	System	20 Aug 2020 21:02:10
User entered 'No interference with activity (1)'	System	20 Aug 2020 21:02:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-20T14:02:08', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '363df6c4-7c0b-4dde-ba57-0325e7a3a008'	System	20 Aug 2020 21:02:10
User entered '20 Aug 2020 14:02'	System	20 Aug 2020 21:02:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	20 Aug 2020 06:59:59
User entered 'Day 17'	System	20 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-21T12:01:23', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '44f25068-6419-4d72-82b5-e36ae69d180c'	System	21 Aug 2020 19:01:29
User entered 'No interference with activity (1)'	System	21 Aug 2020 19:01:29

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-21T12:01:26', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '44f25068-6419-4d72-82b5-e36ae69d180c'	System	21 Aug 2020 19:01:29
User entered '21 Aug 2020 12:01'	System	21 Aug 2020 19:01:29

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	20 Aug 2020 21:02:10
User entered 'Day 18'	System	20 Aug 2020 21:02:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-22T15:55:05', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd23752a1-cb74-4d7b-9ef6-44be4627194b'	System	22 Aug 2020 22:55:11
User entered 'No interference with activity (1)'	System	22 Aug 2020 22:55:11

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-22T15:55:08', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd23752a1-cb74-4d7b-9ef6-44be4627194b'	System	22 Aug 2020 22:55:11
User entered '22 Aug 2020 15:55'	System	22 Aug 2020 22:55:11

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 21:02:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 21:02:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	21 Aug 2020 19:01:29
User entered 'Day 19'	System	21 Aug 2020 19:01:29

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-23T13:21:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd3b4b3a6-a09c-4eaa-a251-4840e6c58748'	System	23 Aug 2020 20:21:36
User entered 'Some interference with activity (2)'	System	23 Aug 2020 20:21:36

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-23T13:21:31', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd3b4b3a6-a09c-4eaa-a251-4840e6c58748'	System	23 Aug 2020 20:21:36
User entered '23 Aug 2020 13:21'	System	23 Aug 2020 20:21:36

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:01:29

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:01:29

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	22 Aug 2020 22:55:11
User entered 'Day 20'	System	22 Aug 2020 22:55:11

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-24T13:12:11', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f40e9cba-e1d7-44f8-80b7-9fc09931a00a'	System	24 Aug 2020 20:12:18
User entered 'No interference with activity (1)'	System	24 Aug 2020 20:12:18

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-24T13:12:15', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f40e9cba-e1d7-44f8-80b7-9fc09931a00a'	System	24 Aug 2020 20:12:18
User entered '24 Aug 2020 13:12'	System	24 Aug 2020 20:12:18

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 22:55:11

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 22:55:11

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	23 Aug 2020 20:21:36
User entered 'Day 21'	System	23 Aug 2020 20:21:36

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-25T12:10:04', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '5e340ce6-653d-4531-afcb-e773dfefd653'	System	25 Aug 2020 19:10:10
User entered 'No interference with activity (1)'	System	25 Aug 2020 19:10:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-25T12:10:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '5e340ce6-653d-4531-afcb-e773dfefd653'	System	25 Aug 2020 19:10:10
User entered '25 Aug 2020 12:10'	System	25 Aug 2020 19:10:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 20:21:36

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 20:21:36

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	24 Aug 2020 20:12:18
User entered 'Day 22'	System	24 Aug 2020 20:12:18

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:12:18

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:12:18

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	25 Aug 2020 19:10:10
User entered 'Day 23'	System	25 Aug 2020 19:10:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-27T12:15:30', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '04d4ea33-dd2e-4d05-8f7f-d94af2958ac3'	System	27 Aug 2020 19:15:39
User entered 'No interference with activity (1)'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-27T12:15:33', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '04d4ea33-dd2e-4d05-8f7f-d94af2958ac3'	System	27 Aug 2020 19:15:39
User entered '27 Aug 2020 12:15'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:10:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:10:10

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	27 Aug 2020 19:15:39
User entered 'Day 24'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-28T22:44:57', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6464bba4-03e4-4670-bdfd-db0019eba5d5'	System	29 Aug 2020 05:45:08
User entered 'Some interference with activity (2)'	System	29 Aug 2020 05:45:08

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-28T22:45:01', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6464bba4-03e4-4670-bdfd-db0019eba5d5'	System	29 Aug 2020 05:45:08
User entered '28 Aug 2020 22:45'	System	29 Aug 2020 05:45:08

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	27 Aug 2020 19:15:39
User entered 'Day 25'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-29T12:02:14', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9657dbff-0d95-4a62-9f61-7154341b923e'	System	29 Aug 2020 19:02:20
User entered 'No interference with activity (1)'	System	29 Aug 2020 19:02:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-29T12:02:17', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9657dbff-0d95-4a62-9f61-7154341b923e'	System	29 Aug 2020 19:02:20
User entered '29 Aug 2020 12:02'	System	29 Aug 2020 19:02:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	29 Aug 2020 05:45:08
User entered 'Day 26'	System	29 Aug 2020 05:45:08

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-30T12:02:54', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '3a4f3e3d-6d27-4def-9e5a-d9eff637fc2a'	System	30 Aug 2020 19:03:03
User entered 'No interference with activity (1)'	System	30 Aug 2020 19:03:03

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-30T12:02:57', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '3a4f3e3d-6d27-4def-9e5a-d9eff637fc2a'	System	30 Aug 2020 19:03:03
User entered '30 Aug 2020 12:02'	System	30 Aug 2020 19:03:03

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 05:45:08

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 05:45:08

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	29 Aug 2020 19:02:20
User entered 'Day 27'	System	29 Aug 2020 19:02:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-31T12:59:43', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b9258a5c-0389-49ea-af3c-797a08aa3e85'	System	31 Aug 2020 19:59:50
User entered 'No interference with activity (1)'	System	31 Aug 2020 19:59:50

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-31T12:59:47', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b9258a5c-0389-49ea-af3c-797a08aa3e85'	System	31 Aug 2020 19:59:50
User entered '31 Aug 2020 12:59'	System	31 Aug 2020 19:59:50

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:02:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:02:20

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	30 Aug 2020 19:03:03
User entered 'Day 28'	System	30 Aug 2020 19:03:03

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-01T12:09:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '31eb2e76-2414-45cd-a70d-130fff30533a'	System	01 Sep 2020 19:09:12
User entered 'No interference with activity (1)'	System	01 Sep 2020 19:09:12

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-01T12:09:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '31eb2e76-2414-45cd-a70d-130fff30533a'	System	01 Sep 2020 19:09:12
User entered '01 Sep 2020 12:09'	System	01 Sep 2020 19:09:12

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 19:03:03

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 19:03:03

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	31 Aug 2020 19:59:50
User entered 'Day 29'	System	31 Aug 2020 19:59:50

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:09:10

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T12:22:52', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7d825dbd-3cde-4d0d-b300-029c3b5d65f9'	System	02 Sep 2020 19:23:08
User entered 'No interference with activity (1)'	System	02 Sep 2020 19:23:08

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T12:23:01', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7d825dbd-3cde-4d0d-b300-029c3b5d65f9'	System	02 Sep 2020 19:23:08
User entered '02 Sep 2020 12:23'	System	02 Sep 2020 19:23:08

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:59:50

US3112113

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:59:50

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	12 Aug 2020 03:00:04
User entered 'Day 8'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-12T15:51:18', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '2ccfb6e7-b2bc-4826-b356-a750ebf7bb95'	System	12 Aug 2020 22:51:25
User entered 'No (N)'	System	12 Aug 2020 22:51:25

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-12T15:51:20', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '2ccfb6e7-b2bc-4826-b356-a750ebf7bb95'	System	12 Aug 2020 22:51:25
User entered '12 Aug 2020 15:51'	System	12 Aug 2020 22:51:25

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	12 Aug 2020 03:00:04
User entered 'Day 9'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-13T22:32:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd4b75cfc-1e4c-46c2-bee8-b9a3268e4604'	System	14 Aug 2020 05:32:46
User entered 'No (N)'	System	14 Aug 2020 05:32:46

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-13T22:32:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd4b75cfc-1e4c-46c2-bee8-b9a3268e4604'	System	14 Aug 2020 05:32:46
User entered '13 Aug 2020 22:32'	System	14 Aug 2020 05:32:46

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 03:00:04

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	12 Aug 2020 22:51:16
User entered 'Day 10'	System	12 Aug 2020 22:51:16

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-14T12:15:12', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b6e64168-70d2-4387-a47a-cf1805ec4bab'	System	14 Aug 2020 19:15:19
User entered 'No (N)'	System	14 Aug 2020 19:15:19

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-14T12:15:16', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b6e64168-70d2-4387-a47a-cf1805ec4bab'	System	14 Aug 2020 19:15:19
User entered '14 Aug 2020 12:15'	System	14 Aug 2020 19:15:19

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 22:51:16

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 22:51:16

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	14 Aug 2020 05:32:31
User entered 'Day 11'	System	14 Aug 2020 05:32:31

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 05:32:31

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 05:32:31

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	14 Aug 2020 19:15:12
User entered 'Day 12'	System	14 Aug 2020 19:15:12

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-16T17:35:04', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '8f0bce7d-199f-40bd-9b54-a8b1dad6a985'	System	17 Aug 2020 00:35:13
User entered 'No (N)'	System	17 Aug 2020 00:35:13

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-16T17:35:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '8f0bce7d-199f-40bd-9b54-a8b1dad6a985'	System	17 Aug 2020 00:35:13
User entered '16 Aug 2020 17:35'	System	17 Aug 2020 00:35:13

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:15:12

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:15:12

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	17 Aug 2020 00:35:02
User entered 'Day 13'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-18T10:06:22', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6ff22f49-703c-4ca5-8ca1-0bdf560692c6'	System	18 Aug 2020 17:06:27
User entered 'No (N)'	System	18 Aug 2020 17:06:27

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-18T10:06:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6ff22f49-703c-4ca5-8ca1-0bdf560692c6'	System	18 Aug 2020 17:06:27
User entered '18 Aug 2020 10:06'	System	18 Aug 2020 17:06:27

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '17 Aug 2020 12:00'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	17 Aug 2020 00:35:02
User entered 'Day 14'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-18T23:59:58', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7c49a58d-4122-4d73-ad38-498461656547'	System	19 Aug 2020 07:00:06
User entered 'No (N)'	System	19 Aug 2020 07:00:06

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-19T00:00:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7c49a58d-4122-4d73-ad38-498461656547'	System	19 Aug 2020 07:00:06
User entered '19 Aug 2020 00:00'	System	19 Aug 2020 07:00:06

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 00:35:02

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	18 Aug 2020 17:06:20
User entered 'Day 15'	System	18 Aug 2020 17:06:20

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-19T23:59:58', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '97884945-720c-40f2-bbdb-e551069bdbab'	System	20 Aug 2020 07:00:09
User entered 'No (N)'	System	20 Aug 2020 07:00:09

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-20T00:00:04', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '97884945-720c-40f2-bbdb-e551069bdbab'	System	20 Aug 2020 07:00:09
User entered '20 Aug 2020 00:00'	System	20 Aug 2020 07:00:09

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:06:20

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:06:20

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	19 Aug 2020 06:59:59
User entered 'Day 16'	System	19 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-20T14:02:33', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f5856fc4-3fcd-4de3-95a2-b9ff8f3c0d6e'	System	20 Aug 2020 21:02:39
User entered 'No (N)'	System	20 Aug 2020 21:02:39

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-20T14:02:36', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f5856fc4-3fcd-4de3-95a2-b9ff8f3c0d6e'	System	20 Aug 2020 21:02:39
User entered '20 Aug 2020 14:02'	System	20 Aug 2020 21:02:39

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	20 Aug 2020 06:59:59
User entered 'Day 17'	System	20 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-21T12:01:14', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd9575eef-29fc-4ced-a8b7-ae80ad451313'	System	21 Aug 2020 19:01:24
User entered 'No (N)'	System	21 Aug 2020 19:01:24

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-21T12:01:17', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd9575eef-29fc-4ced-a8b7-ae80ad451313'	System	21 Aug 2020 19:01:24
User entered '21 Aug 2020 12:01'	System	21 Aug 2020 19:01:24

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 06:59:59

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	20 Aug 2020 21:02:10
User entered 'Day 18'	System	20 Aug 2020 21:02:10

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-22T15:55:20', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f654bc43-ae05-4d2e-a7ed-16c8f3338139'	System	22 Aug 2020 22:55:33
User entered 'No (N)'	System	22 Aug 2020 22:55:33

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-22T15:55:28', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f654bc43-ae05-4d2e-a7ed-16c8f3338139'	System	22 Aug 2020 22:55:33
User entered '22 Aug 2020 15:55'	System	22 Aug 2020 22:55:33

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 21:02:10

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 21:02:10

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	21 Aug 2020 19:01:29
User entered 'Day 19'	System	21 Aug 2020 19:01:29

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-23T13:21:35', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9e5bf6e8-2b34-481e-b5fc-679784fae06c'	System	23 Aug 2020 20:21:41
User entered 'No (N)'	System	23 Aug 2020 20:21:41

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-23T13:21:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9e5bf6e8-2b34-481e-b5fc-679784fae06c'	System	23 Aug 2020 20:21:41
User entered '23 Aug 2020 13:21'	System	23 Aug 2020 20:21:41

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:01:29

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:01:29

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	22 Aug 2020 22:55:11
User entered 'Day 20'	System	22 Aug 2020 22:55:11

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-24T13:12:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0798c3ea-a1fe-4a89-9b5d-02b040fb662d'	System	24 Aug 2020 20:12:30
User entered 'No (N)'	System	24 Aug 2020 20:12:30

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-24T13:12:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0798c3ea-a1fe-4a89-9b5d-02b040fb662d'	System	24 Aug 2020 20:12:30
User entered '24 Aug 2020 13:12'	System	24 Aug 2020 20:12:30

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 22:55:11

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 22:55:11

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	23 Aug 2020 20:21:36
User entered 'Day 21'	System	23 Aug 2020 20:21:36

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-25T12:10:19', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cea0a0fc-4530-4946-ab6e-cdee91e80375'	System	25 Aug 2020 19:10:23
User entered 'No (N)'	System	25 Aug 2020 19:10:23

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-25T12:10:21', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cea0a0fc-4530-4946-ab6e-cdee91e80375'	System	25 Aug 2020 19:10:23
User entered '25 Aug 2020 12:10'	System	25 Aug 2020 19:10:23

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 20:21:36

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 20:21:36

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	24 Aug 2020 20:12:18
User entered 'Day 22'	System	24 Aug 2020 20:12:18

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:12:18

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:12:18

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	25 Aug 2020 19:10:10
User entered 'Day 23'	System	25 Aug 2020 19:10:10

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-27T12:15:39', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '2507bc05-66f9-41bf-9361-da24a3dda4f0'	System	27 Aug 2020 19:15:52
User entered 'Yes (Y)'	System	27 Aug 2020 19:15:52

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-27T12:15:49', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '2507bc05-66f9-41bf-9361-da24a3dda4f0'	System	27 Aug 2020 19:15:52
User entered '27 Aug 2020 12:15'	System	27 Aug 2020 19:15:52

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:10:10

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:10:10

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	27 Aug 2020 19:15:39
User entered 'Day 24'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-28T22:45:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '52d336d5-f6a5-4ebf-9d4e-3747d6f5811d'	System	29 Aug 2020 05:45:10
User entered 'No (N)'	System	29 Aug 2020 05:45:10

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-28T22:45:08', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '52d336d5-f6a5-4ebf-9d4e-3747d6f5811d'	System	29 Aug 2020 05:45:10
User entered '28 Aug 2020 22:45'	System	29 Aug 2020 05:45:10

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	27 Aug 2020 19:15:39
User entered 'Day 25'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-29T12:02:22', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fcadf25f-a2b8-4d89-a273-19da0a76ce70'	System	29 Aug 2020 19:02:27
User entered 'No (N)'	System	29 Aug 2020 19:02:27

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-29T12:02:25', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fcadf25f-a2b8-4d89-a273-19da0a76ce70'	System	29 Aug 2020 19:02:27
User entered '29 Aug 2020 12:02'	System	29 Aug 2020 19:02:27

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 19:15:39

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	29 Aug 2020 05:45:08
User entered 'Day 26'	System	29 Aug 2020 05:45:08

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-30T12:03:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b0479268-89a4-4d8f-b6ee-32022afbfe1a'	System	30 Aug 2020 19:03:13
User entered 'No (N)'	System	30 Aug 2020 19:03:13

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-30T12:03:10', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b0479268-89a4-4d8f-b6ee-32022afbfe1a'	System	30 Aug 2020 19:03:13
User entered '30 Aug 2020 12:03'	System	30 Aug 2020 19:03:13

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 05:45:08

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 05:45:08

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	29 Aug 2020 19:02:20
User entered 'Day 27'	System	29 Aug 2020 19:02:20

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-31T12:59:52', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '133296b2-5472-4ba1-9b11-364e9ebda73b'	System	31 Aug 2020 20:00:03
User entered 'No (N)'	System	31 Aug 2020 20:00:03

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-08-31T12:59:58', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '133296b2-5472-4ba1-9b11-364e9ebda73b'	System	31 Aug 2020 20:00:03
User entered '31 Aug 2020 12:59'	System	31 Aug 2020 20:00:03

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:02:20

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:02:20

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	30 Aug 2020 19:03:03
User entered 'Day 28'	System	30 Aug 2020 19:03:03

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-01T12:09:15', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '387492bd-347f-478f-9e32-aa5a3b24c49a'	System	01 Sep 2020 19:09:19
User entered 'No (N)'	System	01 Sep 2020 19:09:19

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-01T12:09:17', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '387492bd-347f-478f-9e32-aa5a3b24c49a'	System	01 Sep 2020 19:09:19
User entered '01 Sep 2020 12:09'	System	01 Sep 2020 19:09:19

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 19:03:03

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 19:03:03

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	31 Aug 2020 19:59:50
User entered 'Day 29'	System	31 Aug 2020 19:59:50

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T12:23:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '67506110-fc92-4a2a-960a-9586207fe7b6'	System	02 Sep 2020 19:23:30
User entered 'No (N)'	System	02 Sep 2020 19:23:30

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T12:23:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '67506110-fc92-4a2a-960a-9586207fe7b6'	System	02 Sep 2020 19:23:30
User entered '02 Sep 2020 12:23'	System	02 Sep 2020 19:23:30

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:59:50

US3112113

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:59:50

US3112113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:43:04

US3112113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 14:43:04

US3112113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:43:04

US3112113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 14:43:04

US3112113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 14:43:11

US3112113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'I'	System	13 Aug 2020 14:43:11

US3112113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Yes (Y)'	Laurie Han-Conrad (b) (4)	19 Aug 2020 18:01:21

US3112113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered '19 Aug 2020'	Laurie Han-Conrad (b) (4)	19 Aug 2020 18:01:21

US3112113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Contact Made (CONTACT MADE)'	Laurie Han-Conrad (b) (4)	19 Aug 2020 18:01:21

US3112113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered empty.	Laurie Han-Conrad (b) (4)	19 Aug 2020 18:01:21

US3112113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Yes (Y)'	Laurie Han-Conrad (b) (4)	19 Aug 2020 18:01:29

US3112113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'I'	System	19 Aug 2020 18:01:29

US3112113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:47:02

US3112113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered '26 Aug 2020'	Karen Mylerberg (b) (4)	26 Aug 2020 16:47:02

US3112113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:47:02

US3112113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:47:02

US3112113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:47:08

US3112113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'I'	System	26 Aug 2020 16:47:08

US3112113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:30

US3112113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:30

US3112113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:30

US3112113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'VISIT2'	System	02 Sep 2020 20:53:30

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '2 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '11:41'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '2 Sep 2020 11:41'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '98.7' F	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '71'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'bpm'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '16'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'breaths/min'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '144'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'mmHg'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '084'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'mmHg'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '2 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '14:22'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '2 Sep 2020 14:22'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '98.3' F	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '78'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'bpm'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '16'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'breaths/min'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '118'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'mmHg'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '078'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'mmHg'	System	05 Sep 2020 17:41:04

US3112113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	19 Oct 2020 14:40:11
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:10

US3112113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 14:40:11
User entered empty.	(b) (4)	
	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:10
	(b) (4)	

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '13:47'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '2 Sep 2020 13:47'	System	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'ONCE'	System	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 20:53:48

US3112113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:52

US3112113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '2 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:52

US3112113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '12:25'	Karen Mylerberg (b) (4)	05 Sep 2020 17:41:52

US3112113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '2 Sep 2020 12:25'	System	05 Sep 2020 17:41:52

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:09:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '2 Sep 2020'	Karen Mylerberg (b) (4)	05 Sep 2020 17:42:11

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:42:11

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:42:11

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '12:51'	Karen Mylerberg (b) (4)	05 Sep 2020 17:42:11

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '2 Sep 2020 12:51'	System	05 Sep 2020 17:42:11

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:42:11

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'No (N)'	Karen Mylerberg (b) (4)	05 Sep 2020 17:42:11

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	Karen Mylerberg (b) (4)	05 Sep 2020 17:42:11

US3112113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered empty.	System	05 Sep 2020 17:42:11

US3112113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:53:55

US3112113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'I'	System	02 Sep 2020 20:53:55

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:20:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf59a52b-f12e-4ce7-9381-100a4b0f20ee'	System	02 Sep 2020 21:21:01
User entered 'Yes (Y)'	System	02 Sep 2020 21:21:01

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:20:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf59a52b-f12e-4ce7-9381-100a4b0f20ee' User entered '98.3'	System	02 Sep 2020 21:21:01
	System	02 Sep 2020 21:21:01

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:20:49', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf59a52b-f12e-4ce7-9381-100a4b0f20ee'	System	02 Sep 2020 21:21:01
User entered 'No (N)'	System	02 Sep 2020 21:21:01

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:20:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf59a52b-f12e-4ce7-9381-100a4b0f20ee'	System	02 Sep 2020 21:21:01
User entered '02 Sep 2020 14:20'	System	02 Sep 2020 21:21:01

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 14:07'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 16:37'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:27:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ce92ce34-28b1-4074-ade0-fb7f1416f311'	System	03 Sep 2020 04:27:46
User entered 'Yes (Y)'	System	03 Sep 2020 04:27:46

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:27:34', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ce92ce34-28b1-4074-ade0-fb7f1416f311'	System	03 Sep 2020 04:27:46
User entered '98.2'	System	03 Sep 2020 04:27:46

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:27:40', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ce92ce34-28b1-4074-ade0-fb7f1416f311'	System	03 Sep 2020 04:27:46
User entered 'No (N)'	System	03 Sep 2020 04:27:46

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:27:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ce92ce34-28b1-4074-ade0-fb7f1416f311'	System	03 Sep 2020 04:27:46
User entered '02 Sep 2020 21:27'	System	03 Sep 2020 04:27:46

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 17:32'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 2'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:04:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6cc776bf-90fb-4ee7-b850-e71966b632c5'	System	04 Sep 2020 02:05:13
User entered 'Yes (Y)'	System	04 Sep 2020 02:05:13

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:04:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6cc776bf-90fb-4ee7-b850-e71966b632c5'	System	04 Sep 2020 02:05:13
User entered '98.5'	System	04 Sep 2020 02:05:13

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:04:59', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6cc776bf-90fb-4ee7-b850-e71966b632c5'	System	04 Sep 2020 02:05:13
User entered 'No (N)'	System	04 Sep 2020 02:05:13

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:05:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6cc776bf-90fb-4ee7-b850-e71966b632c5'	System	04 Sep 2020 02:05:13
User entered '03 Sep 2020 19:05'	System	04 Sep 2020 02:05:13

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 3'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:56:20', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fa1d94c9-7ad3-4fdc-8d4d-1235dead2b6d'	System	05 Sep 2020 01:57:16
User entered 'Yes (Y)'	System	05 Sep 2020 01:57:16

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:57:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fa1d94c9-7ad3-4fdc-8d4d-1235dead2b6d' User entered '98.5'	System	05 Sep 2020 01:57:16
	System	05 Sep 2020 01:57:16

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:57:10', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fa1d94c9-7ad3-4fdc-8d4d-1235dead2b6d'	System	05 Sep 2020 01:57:16
User entered 'No (N)'	System	05 Sep 2020 01:57:16

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:57:13', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fa1d94c9-7ad3-4fdc-8d4d-1235dead2b6d'	System	05 Sep 2020 01:57:16
User entered '04 Sep 2020 18:57'	System	05 Sep 2020 01:57:16

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 4'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:34:54', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7a79d30e-44a8-4ee5-9a5c-bcb7a94fc39a'	System	06 Sep 2020 00:35:14
User entered 'Yes (Y)'	System	06 Sep 2020 00:35:14

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:03', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7a79d30e-44a8-4ee5-9a5c-bcb7a94fc39a'	System	06 Sep 2020 00:35:14
User entered '97.6'	System	06 Sep 2020 00:35:14

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7a79d30e-44a8-4ee5-9a5c-bcb7a94fc39a'	System	06 Sep 2020 00:35:14
User entered 'No (N)'	System	06 Sep 2020 00:35:14

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:10', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '7a79d30e-44a8-4ee5-9a5c-bcb7a94fc39a'	System	06 Sep 2020 00:35:14
User entered '05 Sep 2020 17:35'	System	06 Sep 2020 00:35:14

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 5'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 6'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 7'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:00:40', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b8de10c7-feac-4e1d-ae49-44f3fdd94206'	System	08 Sep 2020 19:01:40
User entered 'Yes (Y)'	System	08 Sep 2020 19:01:40

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:00:50', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b8de10c7-feac-4e1d-ae49-44f3fdd94206'	System	08 Sep 2020 19:01:40
User entered '95.0'	System	08 Sep 2020 19:01:40

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:00:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b8de10c7-feac-4e1d-ae49-44f3fdd94206'	System	08 Sep 2020 19:01:40
User entered 'No (N)'	System	08 Sep 2020 19:01:40

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:01:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b8de10c7-feac-4e1d-ae49-44f3fdd94206'	System	08 Sep 2020 19:01:40
User entered '08 Sep 2020 12:01'	System	08 Sep 2020 19:01:40

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:21:05', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '697196d2-15b9-4b0d-a30c-16a6bdcf6c1e'	System	02 Sep 2020 21:22:34
User entered 'None (1)'	System	02 Sep 2020 21:22:34

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:21', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '697196d2-15b9-4b0d-a30c-16a6bdcf6c1e'	System	02 Sep 2020 21:22:34
User entered 'No (N)'	System	02 Sep 2020 21:22:34

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '697196d2-15b9-4b0d-a30c-16a6bdcf6c1e'	System	02 Sep 2020 21:22:34
User entered 'No (N)'	System	02 Sep 2020 21:22:34

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:28', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '697196d2-15b9-4b0d-a30c-16a6bdcf6c1e'	System	02 Sep 2020 21:22:34
User entered 'None (1)'	System	02 Sep 2020 21:22:34

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:31', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '697196d2-15b9-4b0d-a30c-16a6bdcf6c1e' User entered '02 Sep 2020 14:22'	System	02 Sep 2020 21:22:34
	System	02 Sep 2020 21:22:34

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 14:07'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 16:37'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:07:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9502181-23ec-442b-b63b-e9bfe0ff22e5'	System	03 Sep 2020 04:08:46
User entered 'None (1)'	System	03 Sep 2020 04:08:46

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:07:59', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9502181-23ec-442b-b63b-e9bfe0ff22e5'	System	03 Sep 2020 04:08:46
User entered 'No (N)'	System	03 Sep 2020 04:08:46

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:08:03', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9502181-23ec-442b-b63b-e9bfe0ff22e5'	System	03 Sep 2020 04:08:46
User entered 'No (N)'	System	03 Sep 2020 04:08:46

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:08:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9502181-23ec-442b-b63b-e9bfe0ff22e5'	System	03 Sep 2020 04:08:46
User entered 'None (1)'	System	03 Sep 2020 04:08:46

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:08:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a9502181-23ec-442b-b63b-e9bfe0ff22e5'	System	03 Sep 2020 04:08:46
User entered '02 Sep 2020 21:08'	System	03 Sep 2020 04:08:46

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 17:32'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 2'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:06:08', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '4af2a244-a204-4f36-b07c-7d9b164c0add'	System	04 Sep 2020 02:06:21
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 02:06:21

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:05:38', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '4af2a244-a204-4f36-b07c-7d9b164c0add'	System	04 Sep 2020 02:06:21
User entered 'No (N)'	System	04 Sep 2020 02:06:21

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:05:42', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '4af2a244-a204-4f36-b07c-7d9b164c0add'	System	04 Sep 2020 02:06:21
User entered 'No (N)'	System	04 Sep 2020 02:06:21

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:05:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '4af2a244-a204-4f36-b07c-7d9b164c0add'	System	04 Sep 2020 02:06:21
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 02:06:21

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:06:18', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '4af2a244-a204-4f36-b07c-7d9b164c0add'	System	04 Sep 2020 02:06:21
User entered '03 Sep 2020 19:06'	System	04 Sep 2020 02:06:21

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 3'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:57:29', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b0091d27-967c-4016-9eab-5ca7f0da1673'	System	05 Sep 2020 01:57:57
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 01:57:57

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:57:32', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b0091d27-967c-4016-9eab-5ca7f0da1673'	System	05 Sep 2020 01:57:57
User entered 'No (N)'	System	05 Sep 2020 01:57:57

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:57:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b0091d27-967c-4016-9eab-5ca7f0da1673'	System	05 Sep 2020 01:57:57
User entered 'No (N)'	System	05 Sep 2020 01:57:57

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:57:50', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b0091d27-967c-4016-9eab-5ca7f0da1673'	System	05 Sep 2020 01:57:57
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 01:57:57

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:57:54', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b0091d27-967c-4016-9eab-5ca7f0da1673'	System	05 Sep 2020 01:57:57
User entered '04 Sep 2020 18:57'	System	05 Sep 2020 01:57:57

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 4'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:34:10', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '78747cc6-e5d8-4208-96ee-8bb0078039c0'	System	06 Sep 2020 00:34:44
User entered 'None (1)'	System	06 Sep 2020 00:34:44

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:34:13', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '78747cc6-e5d8-4208-96ee-8bb0078039c0'	System	06 Sep 2020 00:34:44
User entered 'No (N)'	System	06 Sep 2020 00:34:44

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:34:17', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '78747cc6-e5d8-4208-96ee-8bb0078039c0'	System	06 Sep 2020 00:34:44
User entered 'No (N)'	System	06 Sep 2020 00:34:44

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:34:32', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '78747cc6-e5d8-4208-96ee-8bb0078039c0'	System	06 Sep 2020 00:34:44
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 00:34:44

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:34:38', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '78747cc6-e5d8-4208-96ee-8bb0078039c0'	System	06 Sep 2020 00:34:44
User entered '05 Sep 2020 17:34'	System	06 Sep 2020 00:34:44

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 5'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-06T23:03:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '337a8a5c-12d3-431e-acea-54075155d9f1'	System	07 Sep 2020 06:04:04
User entered 'None (1)'	System	07 Sep 2020 06:04:04

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-06T23:03:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '337a8a5c-12d3-431e-acea-54075155d9f1'	System	07 Sep 2020 06:04:04
User entered 'No (N)'	System	07 Sep 2020 06:04:04

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-06T23:03:48', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '337a8a5c-12d3-431e-acea-54075155d9f1'	System	07 Sep 2020 06:04:04
User entered 'No (N)'	System	07 Sep 2020 06:04:04

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-06T23:03:56', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '337a8a5c-12d3-431e-acea-54075155d9f1'	System	07 Sep 2020 06:04:04
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 06:04:04

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-06T23:04:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '337a8a5c-12d3-431e-acea-54075155d9f1'	System	07 Sep 2020 06:04:04
User entered '06 Sep 2020 23:04'	System	07 Sep 2020 06:04:04

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 6'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:00:17', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bf3c211c-ba4c-4aa4-a566-1311ec77b1a5'	System	08 Sep 2020 09:01:10
User entered 'None (1)'	System	08 Sep 2020 09:01:10

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:00:26', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bf3c211c-ba4c-4aa4-a566-1311ec77b1a5'	System	08 Sep 2020 09:01:10
User entered 'No (N)'	System	08 Sep 2020 09:01:10

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:00:29', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bf3c211c-ba4c-4aa4-a566-1311ec77b1a5'	System	08 Sep 2020 09:01:10
User entered 'No (N)'	System	08 Sep 2020 09:01:10

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:00:40', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bf3c211c-ba4c-4aa4-a566-1311ec77b1a5'	System	08 Sep 2020 09:01:10
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 09:01:10

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:01:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'bf3c211c-ba4c-4aa4-a566-1311ec77b1a5'	System	08 Sep 2020 09:01:10
User entered '08 Sep 2020 02:01'	System	08 Sep 2020 09:01:10

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 7'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:01:43', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '562f8fec-ff24-4e64-8467-6f66690e7879'	System	08 Sep 2020 19:02:40
User entered 'None (1)'	System	08 Sep 2020 19:02:40

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:01:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '562f8fec-ff24-4e64-8467-6f66690e7879'	System	08 Sep 2020 19:02:40
User entered 'No (N)'	System	08 Sep 2020 19:02:40

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:02:30', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '562f8fec-ff24-4e64-8467-6f66690e7879'	System	08 Sep 2020 19:02:40
User entered 'No (N)'	System	08 Sep 2020 19:02:40

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:02:34', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '562f8fec-ff24-4e64-8467-6f66690e7879'	System	08 Sep 2020 19:02:40
User entered 'None (1)'	System	08 Sep 2020 19:02:40

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:02:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '562f8fec-ff24-4e64-8467-6f66690e7879'	System	08 Sep 2020 19:02:40
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 19:02:40

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e19d6ecc-8664-4780-bdb7-27396c91af74'	System	02 Sep 2020 21:23:08
User entered 'None (0)'	System	02 Sep 2020 21:23:08

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:43', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e19d6ecc-8664-4780-bdb7-27396c91af74'	System	02 Sep 2020 21:23:08
User entered 'No interference with activity (1)'	System	02 Sep 2020 21:23:08

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:46', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e19d6ecc-8664-4780-bdb7-27396c91af74'	System	02 Sep 2020 21:23:08
User entered 'None (0)'	System	02 Sep 2020 21:23:08

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:52', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e19d6ecc-8664-4780-bdb7-27396c91af74'	System	02 Sep 2020 21:23:08
User entered 'Some interference with activity (2)'	System	02 Sep 2020 21:23:08

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e19d6ecc-8664-4780-bdb7-27396c91af74'	System	02 Sep 2020 21:23:08
User entered 'None (0)'	System	02 Sep 2020 21:23:08

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:22:58', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e19d6ecc-8664-4780-bdb7-27396c91af74'	System	02 Sep 2020 21:23:08
User entered 'None (0)'	System	02 Sep 2020 21:23:08

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:23:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e19d6ecc-8664-4780-bdb7-27396c91af74'	System	02 Sep 2020 21:23:08
User entered 'No (N)'	System	02 Sep 2020 21:23:08

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T14:23:05', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'e19d6ecc-8664-4780-bdb7-27396c91af74'	System	02 Sep 2020 21:23:08
User entered '02 Sep 2020 14:23'	System	02 Sep 2020 21:23:08

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 14:07'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 16:37'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:27:52', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ab6285f5-96bb-46bd-b1c5-51bf2dab332d'	System	03 Sep 2020 04:28:16
User entered 'None (0)'	System	03 Sep 2020 04:28:16

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:27:56', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ab6285f5-96bb-46bd-b1c5-51bf2dab332d'	System	03 Sep 2020 04:28:16
User entered 'No interference with activity (1)'	System	03 Sep 2020 04:28:16

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:28:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ab6285f5-96bb-46bd-b1c5-51bf2dab332d'	System	03 Sep 2020 04:28:16
User entered 'None (0)'	System	03 Sep 2020 04:28:16

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:28:02', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ab6285f5-96bb-46bd-b1c5-51bf2dab332d'	System	03 Sep 2020 04:28:16
User entered 'None (0)'	System	03 Sep 2020 04:28:16

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:28:04', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ab6285f5-96bb-46bd-b1c5-51bf2dab332d'	System	03 Sep 2020 04:28:16
User entered 'None (0)'	System	03 Sep 2020 04:28:16

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:28:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ab6285f5-96bb-46bd-b1c5-51bf2dab332d'	System	03 Sep 2020 04:28:16
User entered 'None (0)'	System	03 Sep 2020 04:28:16

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:28:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ab6285f5-96bb-46bd-b1c5-51bf2dab332d'	System	03 Sep 2020 04:28:16
User entered 'No (N)'	System	03 Sep 2020 04:28:16

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-02T21:28:12', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ab6285f5-96bb-46bd-b1c5-51bf2dab332d'	System	03 Sep 2020 04:28:16
User entered '02 Sep 2020 21:28'	System	03 Sep 2020 04:28:16

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '02 Sep 2020 17:32'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 2'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:06:26', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '58c7b833-b791-4da0-b58a-b5134af2fbc7'	System	04 Sep 2020 02:07:04
User entered 'No interference with activity (1)'	System	04 Sep 2020 02:07:04

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:06:33', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '58c7b833-b791-4da0-b58a-b5134af2fbc7'	System	04 Sep 2020 02:07:04
User entered 'Significant; prevents daily activity (3)'	System	04 Sep 2020 02:07:04

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:06:38', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '58c7b833-b791-4da0-b58a-b5134af2fbc7'	System	04 Sep 2020 02:07:04
User entered 'Some interference with activity (2)'	System	04 Sep 2020 02:07:04

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:06:45', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '58c7b833-b791-4da0-b58a-b5134af2fbc7'	System	04 Sep 2020 02:07:04
User entered 'Some interference with activity (2)'	System	04 Sep 2020 02:07:04

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:06:49', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '58c7b833-b791-4da0-b58a-b5134af2fbc7'	System	04 Sep 2020 02:07:04
User entered 'None (0)'	System	04 Sep 2020 02:07:04

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:06:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '58c7b833-b791-4da0-b58a-b5134af2fbc7'	System	04 Sep 2020 02:07:04
User entered 'None (0)'	System	04 Sep 2020 02:07:04

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:06:56', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '58c7b833-b791-4da0-b58a-b5134af2fbc7'	System	04 Sep 2020 02:07:04
User entered 'No (N)'	System	04 Sep 2020 02:07:04

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-03T19:07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '58c7b833-b791-4da0-b58a-b5134af2fbc7'	System	04 Sep 2020 02:07:04
User entered '03 Sep 2020 19:07'	System	04 Sep 2020 02:07:04

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 3'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:58:03', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0d6cdca7-8b43-47f0-a8ef-d7c5661f1abe'	System	05 Sep 2020 01:58:36
User entered 'None (0)'	System	05 Sep 2020 01:58:36

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:58:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0d6cdca7-8b43-47f0-a8ef-d7c5661f1abe'	System	05 Sep 2020 01:58:36
User entered 'Some interference with activity (2)'	System	05 Sep 2020 01:58:36

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:58:13', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0d6cdca7-8b43-47f0-a8ef-d7c5661f1abe'	System	05 Sep 2020 01:58:36
User entered 'Some interference with activity (2)'	System	05 Sep 2020 01:58:36

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:58:18', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0d6cdca7-8b43-47f0-a8ef-d7c5661f1abe'	System	05 Sep 2020 01:58:36
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:58:36

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:58:21', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0d6cdca7-8b43-47f0-a8ef-d7c5661f1abe'	System	05 Sep 2020 01:58:36
User entered 'None (0)'	System	05 Sep 2020 01:58:36

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:58:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0d6cdca7-8b43-47f0-a8ef-d7c5661f1abe'	System	05 Sep 2020 01:58:36
User entered 'None (0)'	System	05 Sep 2020 01:58:36

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:58:28', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0d6cdca7-8b43-47f0-a8ef-d7c5661f1abe'	System	05 Sep 2020 01:58:36
User entered 'No (N)'	System	05 Sep 2020 01:58:36

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-04T18:58:33', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0d6cdca7-8b43-47f0-a8ef-d7c5661f1abe'	System	05 Sep 2020 01:58:36
User entered '04 Sep 2020 18:58'	System	05 Sep 2020 01:58:36

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 4'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:16', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f1aac9ac-e720-4fbf-bc52-d5b9940ae43e' User entered 'None (0)'	System	06 Sep 2020 00:35:44
	System	06 Sep 2020 00:35:44

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:20', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f1aac9ac-e720-4fbf-bc52-d5b9940ae43e'	System	06 Sep 2020 00:35:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 00:35:44

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:25', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f1aac9ac-e720-4fbf-bc52-d5b9940ae43e'	System	06 Sep 2020 00:35:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 00:35:44

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:28', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f1aac9ac-e720-4fbf-bc52-d5b9940ae43e' User entered 'None (0)'	System	06 Sep 2020 00:35:44
	System	06 Sep 2020 00:35:44

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:31', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f1aac9ac-e720-4fbf-bc52-d5b9940ae43e'	System	06 Sep 2020 00:35:44
User entered 'None (0)'	System	06 Sep 2020 00:35:44

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:34', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f1aac9ac-e720-4fbf-bc52-d5b9940ae43e' User entered 'None (0)'	System	06 Sep 2020 00:35:44
	System	06 Sep 2020 00:35:44

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f1aac9ac-e720-4fbf-bc52-d5b9940ae43e'	System	06 Sep 2020 00:35:44
User entered 'No (N)'	System	06 Sep 2020 00:35:44

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-05T17:35:40', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f1aac9ac-e720-4fbf-bc52-d5b9940ae43e'	System	06 Sep 2020 00:35:44
User entered '05 Sep 2020 17:35'	System	06 Sep 2020 00:35:44

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 5'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 6'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:01:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '99198ab0-9bc8-4b24-8697-17b963e09b63'	System	08 Sep 2020 09:02:00
User entered 'None (0)'	System	08 Sep 2020 09:02:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:01:36', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '99198ab0-9bc8-4b24-8697-17b963e09b63'	System	08 Sep 2020 09:02:00
User entered 'Some interference with activity (2)'	System	08 Sep 2020 09:02:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:01:39', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '99198ab0-9bc8-4b24-8697-17b963e09b63'	System	08 Sep 2020 09:02:00
User entered 'None (0)'	System	08 Sep 2020 09:02:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:01:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '99198ab0-9bc8-4b24-8697-17b963e09b63'	System	08 Sep 2020 09:02:00
User entered 'None (0)'	System	08 Sep 2020 09:02:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:01:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '99198ab0-9bc8-4b24-8697-17b963e09b63'	System	08 Sep 2020 09:02:00
User entered 'None (0)'	System	08 Sep 2020 09:02:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:01:46', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '99198ab0-9bc8-4b24-8697-17b963e09b63'	System	08 Sep 2020 09:02:00
User entered 'None (0)'	System	08 Sep 2020 09:02:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:01:51', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '99198ab0-9bc8-4b24-8697-17b963e09b63'	System	08 Sep 2020 09:02:00
User entered 'No (N)'	System	08 Sep 2020 09:02:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T02:01:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '99198ab0-9bc8-4b24-8697-17b963e09b63'	System	08 Sep 2020 09:02:00
User entered '08 Sep 2020 02:01'	System	08 Sep 2020 09:02:00

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	02 Sep 2020 20:53:48
User entered 'Day 7'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:02:49', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc86e230-a6eb-461c-98ef-0b5b2159024d'	System	08 Sep 2020 19:03:28
User entered 'None (0)'	System	08 Sep 2020 19:03:28

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:02:52', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc86e230-a6eb-461c-98ef-0b5b2159024d'	System	08 Sep 2020 19:03:28
User entered 'None (0)'	System	08 Sep 2020 19:03:28

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:03:10', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc86e230-a6eb-461c-98ef-0b5b2159024d'	System	08 Sep 2020 19:03:28
User entered 'None (0)'	System	08 Sep 2020 19:03:28

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:03:13', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc86e230-a6eb-461c-98ef-0b5b2159024d'	System	08 Sep 2020 19:03:28
User entered 'None (0)'	System	08 Sep 2020 19:03:28

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:03:15', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc86e230-a6eb-461c-98ef-0b5b2159024d'	System	08 Sep 2020 19:03:28
User entered 'None (0)'	System	08 Sep 2020 19:03:28

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:03:18', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc86e230-a6eb-461c-98ef-0b5b2159024d'	System	08 Sep 2020 19:03:28
User entered 'None (0)'	System	08 Sep 2020 19:03:28

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:03:22', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc86e230-a6eb-461c-98ef-0b5b2159024d'	System	08 Sep 2020 19:03:28
User entered 'No (N)'	System	08 Sep 2020 19:03:28

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-09-08T12:03:25', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fc86e230-a6eb-461c-98ef-0b5b2159024d'	System	08 Sep 2020 19:03:28
User entered '08 Sep 2020 12:03'	System	08 Sep 2020 19:03:28

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:53:48

US3112113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:53:48

US3112113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	16 Sep 2020 23:11:09
User entered 'Yes (Y)'	(b) (4)	
	Karen Mylerberg (b) (4)	16 Sep 2020 23:10:51
	(b) (4)	

US3112113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 23:11:09
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	16 Sep 2020 23:11:09
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4)	16 Sep 2020 23:11:09
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Sep 2020 23:10:51
User entered '16 Sep 2020'	Karen Mylerberg (b) (4)	16 Sep 2020 23:10:51

US3112113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4)	16 Sep 2020 23:11:09
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:10:51

US3112113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered empty.	Karen Mylerberg (b) (4)	16 Sep 2020 23:10:51

US3112113

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:36:25
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:11:16

US3112113

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'I'	System	16 Sep 2020 23:11:16

US3112113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:11:30

US3112113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '16 Sep 2020'	Karen Mylerberg (b) (4)	16 Sep 2020 23:11:30

US3112113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:11:30

US3112113

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	Karen Mylerberg (b) (4)	16 Sep 2020 23:11:30

US3112113

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	16 Sep 2020 23:11:36

US3112113

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'I'	System	16 Sep 2020 23:11:36

US3112113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:56:01

US3112113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:56:01

US3112113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:56:01

US3112113

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:56:01

US3112113

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:56:09

US3112113

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'I'	System	02 Oct 2020 15:56:09

US3112113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:56:28

US3112113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:56:28

US3112113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:56:28

US3112113

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User entered 'VISIT3'	System	02 Oct 2020 15:56:28

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '11:35'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User entered '01 Oct 2020 11:35'	System	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '64'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User entered 'bpm'	System	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '14'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User entered 'breaths/min'	System	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '126'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User entered 'mmHg'	System	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '82'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47
User entered 'mmHg'	System	02 Oct 2020 15:57:25

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47

US3112113

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:47

US3112113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:00:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 15:59:26

US3112113

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:00:12
User entered '01 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 15:59:26

US3112113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:58:27

US3112113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:58:27

US3112113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered '12:00'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:58:27

US3112113

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '01 Oct 2020 12:00'	System	02 Oct 2020 15:58:27

US3112113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:48:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:59:34

US3112113

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered '1'	System	02 Oct 2020 15:59:34

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 64'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-10-07T16:20:50', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '36a418df-5f78-494d-b835-de08cdc43f8c'	System	07 Oct 2020 23:21:40
User entered 'No (N)'	System	07 Oct 2020 23:21:40

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-10-07T16:21:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '36a418df-5f78-494d-b835-de08cdc43f8c'	System	07 Oct 2020 23:21:40
User entered 'No (N)'	System	07 Oct 2020 23:21:40

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-10-07T16:21:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '36a418df-5f78-494d-b835-de08cdc43f8c' User entered '07 Oct 2020 16:21:37'	System	07 Oct 2020 23:21:40
	System	07 Oct 2020 23:21:40

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 71'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-10-12T18:54:48', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b41761ef-bac4-45f8-84b2-cebc59d059ab'	System	13 Oct 2020 01:54:56
User entered 'No (N)'	System	13 Oct 2020 01:54:56

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-10-12T18:54:17', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b41761ef-bac4-45f8-84b2-cebc59d059ab'	System	13 Oct 2020 01:54:56
User entered 'No (N)'	System	13 Oct 2020 01:54:56

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (10c86dec863efa19)', Time: '2020-10-12T18:54:52', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b41761ef-bac4-45f8-84b2-cebc59d059ab' User entered '12 Oct 2020 18:54:52'	System	13 Oct 2020 01:54:56
	System	13 Oct 2020 01:54:56

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 78'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Please 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)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Please 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)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Please 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)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:50:45
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 92'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-11-02T00:03:56', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'de339e5f-bce2-4072-80b7-742e130afd6b'	System	02 Nov 2020 08:04:08
User entered 'No (N)'	System	02 Nov 2020 08:04:08

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-11-02T00:04:01', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'de339e5f-bce2-4072-80b7-742e130afd6b'	System	02 Nov 2020 08:04:08
User entered 'No (N)'	System	02 Nov 2020 08:04:08

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-11-02T00:04:04', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'de339e5f-bce2-4072-80b7-742e130afd6b'	System	02 Nov 2020 08:04:08
User entered '02 Nov 2020 00:04:04'	System	02 Nov 2020 08:04:08

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 99'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-11-09T00:04:26', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '39514d51-07a9-4a29-b413-8e19090e0afe'	System	09 Nov 2020 08:05:08
User entered 'Yes (Y)'	System	09 Nov 2020 08:05:08

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-11-09T00:04:30', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '39514d51-07a9-4a29-b413-8e19090e0afe'	System	09 Nov 2020 08:05:08
User entered 'No (N)'	System	09 Nov 2020 08:05:08

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-11-09T00:04:38', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '39514d51-07a9-4a29-b413-8e19090e0afe'	System	09 Nov 2020 08:05:08
User entered 'No (N)'	System	09 Nov 2020 08:05:08

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-11-09T00:04:46', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '39514d51-07a9-4a29-b413-8e19090e0afe'	System	09 Nov 2020 08:05:08
User entered 'Yes (Y)'	System	09 Nov 2020 08:05:08

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-11-09T00:04:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '39514d51-07a9-4a29-b413-8e19090e0afe'	System	09 Nov 2020 08:05:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 08:05:08

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-11-09T00:04:57', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '39514d51-07a9-4a29-b413-8e19090e0afe'	System	09 Nov 2020 08:05:08
User entered '09 Nov 2020 00:04:57'	System	09 Nov 2020 08:05:08

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered 'Day 106'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-11-16T00:01:59', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '772da12d-f04e-4132-bfd3-7b002bd8d96e'	System	16 Nov 2020 08:02:13
User entered 'No (N)'	System	16 Nov 2020 08:02:13

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-11-16T00:02:05', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '772da12d-f04e-4132-bfd3-7b002bd8d96e'	System	16 Nov 2020 08:02:13
User entered 'No (N)'	System	16 Nov 2020 08:02:13

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-11-16T00:02:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '772da12d-f04e-4132-bfd3-7b002bd8d96e'	System	16 Nov 2020 08:02:13
User entered '16 Nov 2020 00:02:09'	System	16 Nov 2020 08:02:13

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 22:04:33

US3112113

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:23:00
Data entry locked.	System	05 Aug 2020 22:04:33
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 22:04:33

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 13:55:27
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Bilateral leg cramping reported at this time. Please see updated Med hx. ' (Site from DM).	Matthew Musikanth (b) (4)	01 Mar 2021 16:34:01
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-11-20T03:50:50', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f9014c2f-d5a7-4a54-9082-6377357a516a'	System	20 Nov 2020 11:51:34
User entered 'Yes (Y)'	System	20 Nov 2020 11:51:34

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2020-11-20T03:50:54', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f9014c2f-d5a7-4a54-9082-6377357a516a'	System	20 Nov 2020 11:51:34
User entered 'No (N)'	System	20 Nov 2020 11:51:34

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2020-11-20T03:51:01', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f9014c2f-d5a7-4a54-9082-6377357a516a'	System	20 Nov 2020 11:51:34
User entered 'No (N)'	System	20 Nov 2020 11:51:34

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2020-11-20T03:51:08', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f9014c2f-d5a7-4a54-9082-6377357a516a'	System	20 Nov 2020 11:51:34
User entered 'Yes (Y)'	System	20 Nov 2020 11:51:34

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Please 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 (3ddb2953c143c2)', Time: '2020-11-20T03:51:16', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f9014c2f-d5a7-4a54-9082-6377357a516a'	System	20 Nov 2020 11:51:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Nov 2020 11:51:34

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-11-20T03:51:22', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f9014c2f-d5a7-4a54-9082-6377357a516a'	System	20 Nov 2020 11:51:34
User entered '20 Nov 2020 03:51:22'	System	20 Nov 2020 11:51:34

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2020-11-28T15:27:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0386285f-7204-47ee-89b2-1ff26b090383'	System	28 Nov 2020 23:27:59
User entered 'No (N)'	System	28 Nov 2020 23:27:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2020-11-28T15:27:48', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0386285f-7204-47ee-89b2-1ff26b090383'	System	28 Nov 2020 23:27:59
User entered 'No (N)'	System	28 Nov 2020 23:27:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-11-28T15:27:53', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0386285f-7204-47ee-89b2-1ff26b090383'	System	28 Nov 2020 23:27:59
User entered '28 Nov 2020 15:27:53'	System	28 Nov 2020 23:27:59

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2020-12-08T08:59:48', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '73b4f2d6-165e-4b52-9403-21660c68726f'	System	08 Dec 2020 19:04:46
User entered 'No (N)'	System	08 Dec 2020 19:04:46

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2020-12-08T11:04:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '73b4f2d6-165e-4b52-9403-21660c68726f'	System	08 Dec 2020 19:04:46
User entered 'No (N)'	System	08 Dec 2020 19:04:46

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-08T11:04:42', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '73b4f2d6-165e-4b52-9403-21660c68726f' User entered '08 Dec 2020 11:04:42'	System	08 Dec 2020 19:04:46
	System	08 Dec 2020 19:04:46

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2020-12-13T09:48:51', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered 'Yes (Y)'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2020-12-13T09:49:07', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered 'No (N)'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2020-12-13T09:49:19', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered 'Yes (Y)'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb9b2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '1'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '1'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '1'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb9b2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '1'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '1'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '1'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-12-13T09:49:41', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '0'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please 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 (3ddb2953c143c2)', Time: '2020-12-13T09:49:56', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2020-12-13T09:50:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered 'Yes (Y)'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Please 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 (3ddb2953c143c2)', Time: '2020-12-13T09:50:10', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2020-12-13T09:50:16', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0575cb91-cdf1-42e1-96be-6a8046af6940'	System	13 Dec 2020 17:50:26
User entered '13 Dec 2020 09:50:16'	System	13 Dec 2020 17:50:26

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddbab2953c143c2)', Time: '2020-12-18T00:34:36', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '56e1719c-a15b-45e4-a984-1ef8279ee775'	System	18 Dec 2020 08:34:53
User entered 'No (N)'	System	18 Dec 2020 08:34:53

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2020-12-18T00:34:45', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '56e1719c-a15b-45e4-a984-1ef8279ee775'	System	18 Dec 2020 08:34:53
User entered 'No (N)'	System	18 Dec 2020 08:34:53

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-18T00:34:50', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '56e1719c-a15b-45e4-a984-1ef8279ee775'	System	18 Dec 2020 08:34:53
User entered '18 Dec 2020 00:34:50'	System	18 Dec 2020 08:34:53

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2020-12-25T00:02:04', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b8aca5e1-259e-4eee-a6f1-7047ce93c2fa'	System	25 Dec 2020 08:02:19
User entered 'No (N)'	System	25 Dec 2020 08:02:19

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2020-12-25T00:02:08', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b8aca5e1-259e-4eee-a6f1-7047ce93c2fa'	System	25 Dec 2020 08:02:19
User entered 'No (N)'	System	25 Dec 2020 08:02:19

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2020-12-25T00:02:16', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'b8aca5e1-259e-4eee-a6f1-7047ce93c2fa'	System	25 Dec 2020 08:02:19
User entered '25 Dec 2020 00:02:16'	System	25 Dec 2020 08:02:19

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-01-01T04:03:37', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fedc66a3-7e7b-4c22-a5d6-90aa7968c11c'	System	01 Jan 2021 12:03:50
User entered 'No (N)'	System	01 Jan 2021 12:03:50

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-01-01T04:03:40', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fedc66a3-7e7b-4c22-a5d6-90aa7968c11c'	System	01 Jan 2021 12:03:50
User entered 'No (N)'	System	01 Jan 2021 12:03:50

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2021-01-01T04:03:44', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'fedc66a3-7e7b-4c22-a5d6-90aa7968c11c' User entered '01 Jan 2021 04:03:44'	System	01 Jan 2021 12:03:50
	System	01 Jan 2021 12:03:50

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-01-08T00:21:21', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9c258e34-27ba-495c-9cf3-5b153b78e10b'	System	08 Jan 2021 08:21:38
User entered 'No (N)'	System	08 Jan 2021 08:21:38

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-01-08T00:21:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9c258e34-27ba-495c-9cf3-5b153b78e10b'	System	08 Jan 2021 08:21:38
User entered 'No (N)'	System	08 Jan 2021 08:21:38

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-01-08T00:21:33', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '9c258e34-27ba-495c-9cf3-5b153b78e10b'	System	08 Jan 2021 08:21:38
User entered '08 Jan 2021 00:21:33'	System	08 Jan 2021 08:21:38

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-01-16T16:37:24', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '235c0dbd-4b58-435c-8bbc-5db06fba9cb9'	System	17 Jan 2021 00:37:36
User entered 'No (N)'	System	17 Jan 2021 00:37:36

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-01-16T16:37:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '235c0dbd-4b58-435c-8bbc-5db06fba9cb9'	System	17 Jan 2021 00:37:36
User entered 'No (N)'	System	17 Jan 2021 00:37:36

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-01-16T16:37:32', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '235c0dbd-4b58-435c-8bbc-5db06fba9cb9'	System	17 Jan 2021 00:37:36
User entered '16 Jan 2021 16:37:32'	System	17 Jan 2021 00:37:36

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-01-22T00:01:56', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '18c778a9-afe0-4171-8382-121efe31cdef'	System	22 Jan 2021 08:02:06
User entered 'No (N)'	System	22 Jan 2021 08:02:06

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-01-22T00:01:59', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '18c778a9-afe0-4171-8382-121efe31cdef'	System	22 Jan 2021 08:02:06
User entered 'No (N)'	System	22 Jan 2021 08:02:06

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2021-01-22T00:02:03', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '18c778a9-afe0-4171-8382-121efe31cdef'	System	22 Jan 2021 08:02:06
User entered '22 Jan 2021 00:02:03'	System	22 Jan 2021 08:02:06

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-02-01T17:57:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f73e15f3-c65b-4107-9225-4ce1a6620622'	System	02 Feb 2021 01:57:51
User entered 'No (N)'	System	02 Feb 2021 01:57:51

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-02-01T17:57:43', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f73e15f3-c65b-4107-9225-4ce1a6620622'	System	02 Feb 2021 01:57:51
User entered 'No (N)'	System	02 Feb 2021 01:57:51

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2021-02-01T17:57:47', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f73e15f3-c65b-4107-9225-4ce1a6620622'	System	02 Feb 2021 01:57:51
User entered '01 Feb 2021 17:57:47'	System	02 Feb 2021 01:57:51

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-02-06T14:59:25', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd392eae6-9baf-4dc5-909f-d6c6f42d589b'	System	06 Feb 2021 22:59:36
User entered 'No (N)'	System	06 Feb 2021 22:59:36

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-02-06T14:59:27', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd392eae6-9baf-4dc5-909f-d6c6f42d589b'	System	06 Feb 2021 22:59:36
User entered 'No (N)'	System	06 Feb 2021 22:59:36

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-02-06T14:59:31', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd392eae6-9baf-4dc5-909f-d6c6f42d589b'	System	06 Feb 2021 22:59:36
User entered '06 Feb 2021 14:59:31'	System	06 Feb 2021 22:59:36

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-02-12T02:39:06', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f790c557-e948-4f93-8d83-89023addb4e3'	System	12 Feb 2021 10:39:18
User entered 'No (N)'	System	12 Feb 2021 10:39:18

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-02-12T02:39:09', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f790c557-e948-4f93-8d83-89023addb4e3'	System	12 Feb 2021 10:39:18
User entered 'No (N)'	System	12 Feb 2021 10:39:18

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-02-12T02:39:12', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'f790c557-e948-4f93-8d83-89023addb4e3'	System	12 Feb 2021 10:39:18
User entered '12 Feb 2021 02:39:12'	System	12 Feb 2021 10:39:18

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-02-19T00:14:55', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '8c4abae0-8dab-4d1e-8d3b-3dafa7ba8353'	System	19 Feb 2021 08:15:45
User entered 'Yes (Y)'	System	19 Feb 2021 08:15:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-02-19T00:14:59', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '8c4abae0-8dab-4d1e-8d3b-3dafa7ba8353'	System	19 Feb 2021 08:15:45
User entered 'No (N)'	System	19 Feb 2021 08:15:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-02-19T00:15:04', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '8c4abae0-8dab-4d1e-8d3b-3dafa7ba8353'	System	19 Feb 2021 08:15:45
User entered 'No (N)'	System	19 Feb 2021 08:15:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-02-19T00:15:13', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '8c4abae0-8dab-4d1e-8d3b-3dafa7ba8353'	System	19 Feb 2021 08:15:45
User entered 'Yes (Y)'	System	19 Feb 2021 08:15:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Please 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 (3ddb2953c143c2)', Time: '2021-02-19T00:15:19', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '8c4abae0-8dab-4d1e-8d3b-3dafa7ba8353'	System	19 Feb 2021 08:15:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Feb 2021 08:15:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2021-02-19T00:15:23', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '8c4abae0-8dab-4d1e-8d3b-3dafa7ba8353'	System	19 Feb 2021 08:15:45
User entered '19 Feb 2021 00:15:23'	System	19 Feb 2021 08:15:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-02-26T00:01:31-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ac0a3ed8-f1fd-4ecc-a05b-db3bb91f5607'	System	26 Feb 2021 08:02:07
User entered 'Yes (Y)'	System	26 Feb 2021 08:02:07

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-02-26T00:01:34-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ac0a3ed8-f1fd-4ecc-a05b-db3bb91f5607'	System	26 Feb 2021 08:02:07
User entered 'No (N)'	System	26 Feb 2021 08:02:07

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-02-26T00:01:39-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ac0a3ed8-f1fd-4ecc-a05b-db3bb91f5607'	System	26 Feb 2021 08:02:07
User entered 'No (N)'	System	26 Feb 2021 08:02:07

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-02-26T00:01:46-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ac0a3ed8-f1fd-4ecc-a05b-db3bb91f5607'	System	26 Feb 2021 08:02:07
User entered 'Yes (Y)'	System	26 Feb 2021 08:02:07

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please 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 (3ddb2953c143c2)', Time: '2021-02-26T00:01:49-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ac0a3ed8-f1fd-4ecc-a05b-db3bb91f5607'	System	26 Feb 2021 08:02:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Feb 2021 08:02:07

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-02-26T00:01:53-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'ac0a3ed8-f1fd-4ecc-a05b-db3bb91f5607'	System	26 Feb 2021 08:02:07
User entered '26 Feb 2021 00:01:53'	System	26 Feb 2021 08:02:07

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-03-05T00:04:08-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6f621dc2-dc02-40c3-aea7-ec2129a6854f'	System	05 Mar 2021 08:04:23
User entered 'No (N)'	System	05 Mar 2021 08:04:23

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-03-05T00:04:11-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6f621dc2-dc02-40c3-aea7-ec2129a6854f'	System	05 Mar 2021 08:04:23
User entered 'No (N)'	System	05 Mar 2021 08:04:23

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-03-05T00:04:16-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '6f621dc2-dc02-40c3-aea7-ec2129a6854f'	System	05 Mar 2021 08:04:23
User entered '05 Mar 2021 00:04:16'	System	05 Mar 2021 08:04:23

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-03-12T00:31:58-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf15e70b-c6c3-46a5-9b38-6f049d764598'	System	12 Mar 2021 08:32:51
User entered 'Yes (Y)'	System	12 Mar 2021 08:32:51

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-03-12T00:32:02-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf15e70b-c6c3-46a5-9b38-6f049d764598'	System	12 Mar 2021 08:32:51
User entered 'No (N)'	System	12 Mar 2021 08:32:51

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-03-12T00:32:07-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf15e70b-c6c3-46a5-9b38-6f049d764598'	System	12 Mar 2021 08:32:51
User entered 'No (N)'	System	12 Mar 2021 08:32:51

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-03-12T00:32:14-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf15e70b-c6c3-46a5-9b38-6f049d764598'	System	12 Mar 2021 08:32:51
User entered 'Yes (Y)'	System	12 Mar 2021 08:32:51

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Please 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 (3ddb2953c143c2)', Time: '2021-03-12T00:32:17-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf15e70b-c6c3-46a5-9b38-6f049d764598'	System	12 Mar 2021 08:32:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Mar 2021 08:32:51

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-03-12T00:32:22-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'cf15e70b-c6c3-46a5-9b38-6f049d764598'	System	12 Mar 2021 08:32:51
User entered '12 Mar 2021 00:32:22'	System	12 Mar 2021 08:32:51

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-03-19T00:01:59-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd20b8648-0f1d-4f5c-a0a5-ebfd30026e5e'	System	19 Mar 2021 07:02:12
User entered 'No (N)'	System	19 Mar 2021 07:02:12

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddbab2953c143c2)', Time: '2021-03-19T00:02:03-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd20b8648-0f1d-4f5c-a0a5-ebfd30026e5e'	System	19 Mar 2021 07:02:12
User entered 'No (N)'	System	19 Mar 2021 07:02:12

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2021-03-19T00:02:08-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'd20b8648-0f1d-4f5c-a0a5-ebfd30026e5e' User entered '19 Mar 2021 00:02:08'	System	19 Mar 2021 07:02:12

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-03-26T08:22:15-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0300d5a3-be03-41c3-8406-bcb85c34e36f' User entered 'Yes (Y)'	System	26 Mar 2021 15:23:00
	System	26 Mar 2021 15:23:00

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-03-26T08:22:22-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0300d5a3-be03-41c3-8406-bcb85c34e36f'	System	26 Mar 2021 15:23:00
User entered 'No (N)'	System	26 Mar 2021 15:23:00

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-03-26T08:22:31-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0300d5a3-be03-41c3-8406-bcb85c34e36f' User entered 'No (N)'	System	26 Mar 2021 15:23:00
	System	26 Mar 2021 15:23:00

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-03-26T08:22:35-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0300d5a3-be03-41c3-8406-bcb85c34e36f'	System	26 Mar 2021 15:23:00
User entered 'Yes (Y)'	System	26 Mar 2021 15:23:00

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Please 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 (3ddb2953c143c2)', Time: '2021-03-26T08:22:45-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0300d5a3-be03-41c3-8406-bcb85c34e36f'	System	26 Mar 2021 15:23:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Mar 2021 15:23:00

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-03-26T08:22:48-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '0300d5a3-be03-41c3-8406-bcb85c34e36f' User entered '26 Mar 2021 08:22:48'	System	26 Mar 2021 15:23:00
	System	26 Mar 2021 15:23:00

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-04-05T06:15:16-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '11dd849f-9454-4a76-ac22-a569872f7486'	System	05 Apr 2021 13:15:55
User entered 'Yes (Y)'	System	05 Apr 2021 13:15:55

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-04-05T06:15:20-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '11dd849f-9454-4a76-ac22-a569872f7486'	System	05 Apr 2021 13:15:55
User entered 'No (N)'	System	05 Apr 2021 13:15:55

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-04-05T06:15:24-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '11dd849f-9454-4a76-ac22-a569872f7486'	System	05 Apr 2021 13:15:55
User entered 'No (N)'	System	05 Apr 2021 13:15:55

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-04-05T06:15:29-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '11dd849f-9454-4a76-ac22-a569872f7486'	System	05 Apr 2021 13:15:55
User entered 'Yes (Y)'	System	05 Apr 2021 13:15:55

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Please 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 (3ddb2953c143c2)', Time: '2021-04-05T06:15:38-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '11dd849f-9454-4a76-ac22-a569872f7486'	System	05 Apr 2021 13:15:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Apr 2021 13:15:55

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-04-05T06:15:44-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '11dd849f-9454-4a76-ac22-a569872f7486'	System	05 Apr 2021 13:15:55
User entered '05 Apr 2021 06:15:44'	System	05 Apr 2021 13:15:55

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-04-09T12:50:28-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a788e09f-a5bf-437e-9558-e0996f3e3863'	System	09 Apr 2021 19:50:47
User entered 'No (N)'	System	09 Apr 2021 19:50:47

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-04-09T12:50:32-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a788e09f-a5bf-437e-9558-e0996f3e3863'	System	09 Apr 2021 19:50:47
User entered 'No (N)'	System	09 Apr 2021 19:50:47

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-04-09T12:50:42-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'a788e09f-a5bf-437e-9558-e0996f3e3863' User entered '09 Apr 2021 12:50:42'	System	09 Apr 2021 19:50:47
	System	09 Apr 2021 19:50:47

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-04-18T12:40:51-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'aad5b3d-7964-4210-8da6-a0baf39ad203'	System	18 Apr 2021 19:42:06
User entered 'Yes (Y)'	System	18 Apr 2021 19:42:06

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-04-18T12:40:55-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'aad5b3d-7964-4210-8da6-a0baf39ad203'	System	18 Apr 2021 19:42:06
User entered 'No (N)'	System	18 Apr 2021 19:42:06

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-04-18T12:40:58-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'aadc5b3d-7964-4210-8da6-a0baf39ad203'	System	18 Apr 2021 19:42:06
User entered 'No (N)'	System	18 Apr 2021 19:42:06

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-04-18T12:41:03-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'aad5b3d-7964-4210-8da6-a0baf39ad203'	System	18 Apr 2021 19:42:06
User entered 'Yes (Y)'	System	18 Apr 2021 19:42:06

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Please 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 (3ddb2953c143c2)', Time: '2021-04-18T12:41:08-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'aad5b3d-7964-4210-8da6-a0baf39ad203'	System	18 Apr 2021 19:42:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Apr 2021 19:42:06

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-04-18T12:41:54-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'aad5b3d-7964-4210-8da6-a0baf39ad203'	System	18 Apr 2021 19:42:06
User entered '18 Apr 2021 12:41:54'	System	18 Apr 2021 19:42:06

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[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 (3ddb2953c143c2)', Time: '2021-04-30T00:01:32-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'de0fdd19-84a2-4cf7-b3e9-fcc7d98f9567'	System	30 Apr 2021 07:01:55
User entered 'No (N)'	System	30 Apr 2021 07:01:55

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

Have you been exposed to someone with 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 (3ddb2953c143c2)', Time: '2021-04-30T00:01:35-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'de0fdd19-84a2-4cf7-b3e9-fcc7d98f9567'	System	30 Apr 2021 07:01:55
User entered 'No (N)'	System	30 Apr 2021 07:01:55

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddb2953c143c2)', Time: '2021-04-30T00:01:51-07:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: 'de0fdd19-84a2-4cf7-b3e9-fcc7d98f9567' User entered '30 Apr 2021 00:01:51'	System	30 Apr 2021 07:01:55
	System	30 Apr 2021 07:01:55

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:50:45

US3112113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:50:45
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:50:45

US3112113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:09:10

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2021-03-01T02:46:42-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '130ecffd-2cc5-4f66-9b52-f1f457baaa84'	System	01 Mar 2021 10:46:54
User entered 'No (N)'	System	01 Mar 2021 10:46:54

US3112113

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:09:10

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ddbab2953c143c2)', Time: '2021-03-01T02:46:50-08:00', User OID: 'PatientReportedOutcome (US3112113)', ODM File OID: '130ecffd-2cc5-4f66-9b52-f1f457baaa84'	System	01 Mar 2021 10:46:54
User entered '01 Mar 2021 02:46:50'	System	01 Mar 2021 10:46:54

US3112113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	27 Oct 2020 18:50:44

US3112113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered '27 Oct 2020'	Natalie Moy (b) (4)	27 Oct 2020 18:50:44

US3112113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4)	27 Oct 2020 18:50:44

US3112113

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered empty.	Natalie Moy (b) (4)	27 Oct 2020 18:50:44

US3112113

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:44:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	27 Oct 2020 18:50:48

US3112113

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:00:41
User entered 'I'	System	27 Oct 2020 18:50:48

US3112113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Nov 2020 22:17:26

US3112113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '30 Nov 2020'	Karen Mylerberg (b) (4)	30 Nov 2020 22:17:26

US3112113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	30 Nov 2020 22:17:26

US3112113

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Karen Mylerberg (b) (4)	30 Nov 2020 22:17:26

US3112113

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Nov 2020 22:17:16

US3112113

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User entered 'I'	System	30 Nov 2020 22:17:16

US3112113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:28:49

US3112113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '30 Dec 2020'	Matthew Musikanth (b) (4)	31 Dec 2020 00:28:49

US3112113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:28:49

US3112113

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:28:49

US3112113

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:28:35

US3112113

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User entered 'I'	System	31 Dec 2020 00:28:35

US3112113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Jan 2021 21:58:46

US3112113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '29 Jan 2021'	Matthew Musikanth (b) (4)	29 Jan 2021 21:58:46

US3112113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	29 Jan 2021 21:58:46

US3112113

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 21:58:46

US3112113

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Jan 2021 21:58:52

US3112113

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 12:06:47
User entered 'I'	System	29 Jan 2021 21:58:52

US3112113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Brenda Grande (b) (4)	26 Mar 2021 17:26:01
	(b) (4)	

US3112113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	26 Mar 2021 17:26:01
	(b) (4)	

US3112113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	26 Mar 2021 17:26:01
	(b) (4)	

US3112113

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	26 Mar 2021 17:26:01

US3112113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Brenda Grande (b) (4)	26 Mar 2021 17:26:04
	(b) (4)	

US3112113

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	26 Mar 2021 17:26:04
	(b) (4)	

US3112113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Brenda Grande (b) (4)	26 Mar 2021 17:26:09
	(b) (4)	

US3112113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	26 Mar 2021 17:26:09
	(b) (4)	

US3112113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	26 Mar 2021 17:26:09
	(b) (4)	

US3112113

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:26:09

US3112113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Brenda Grande (b) (4)	26 Mar 2021 17:26:12
	(b) (4)	

US3112113

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 17:26:12

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:10

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:54
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:10:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14 Dec 2020'	Matthew Musikanth (b) (4)	16 Dec 2020 23:33:46

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:10

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:54
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:10:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14:30'	Matthew Musikanth (b) (4)	16 Dec 2020 23:33:46

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:10

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:54
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:10:50
User entered '14 Dec 2020 14:30'	System	16 Dec 2020 23:33:46

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:10

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:54
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:10:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Safety Call (Safety Call)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:33:46

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:10

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:54
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:10:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:33:46

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Day 1 (Day 1)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '09 Dec 2020'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User entered '%'	System	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:35:32

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Day 2 (Day 2)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '10 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User entered '%'	System	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '11 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User entered '%'	System	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Day 4 (Day 4)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '12 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User entered '%'	System	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '13 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User entered '%'	System	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Day 6 (Day 6)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '97'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User entered '%'	System	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '97.9' F	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '15 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'I'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User entered empty.	System	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Day 8 (Day 8)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '16 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User entered '%'	System	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '17 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '95'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User entered '%'	System	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '97.6' F	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:09:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:38
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:03
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:09

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14 Dec 2020'	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:03

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:03

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Dec 2020 17:12:57
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:59
Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:08
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:34:03
User entered empty.	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:03

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14 Dec 2020'	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:03

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:03

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:03

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:03

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:03

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	16 Dec 2020 23:34:03

US3112113

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:10

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 21:11:29
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:11:14
User entered '0'	System	23 Dec 2020 00:01:59

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:09:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User accepted default value 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:09:10

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:09:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '16 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:09:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User accepted default value 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:09:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:09:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:09:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User accepted default value 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:09:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:09:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:09:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User accepted default value 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:09:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:09:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:09:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User accepted default value 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:09:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:09:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:09:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User accepted default value 'Day 21 (Day 21)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:09:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:09:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:09:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User accepted default value 'Day 28 (Day 28)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:09:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:09:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	18 Dec 2020 00:09:37

US3112113

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:36:09

US3112113

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14 Dec 2020'	Matthew Musikanth (b) (4)	16 Dec 2020 23:36:09

US3112113

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Home (Home)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:36:09

US3112113

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User entered 'SICKD1'	System	16 Dec 2020 23:36:09

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14 Dec 2020'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '15:30'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User entered '14 Dec 2020 15:30'	System	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth	16 Dec 2020 23:37:20
DataPoint set to visible.	(b) (4) System	16 Dec 2020 23:36:09

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered missing code ND - Not Done.	Matthew Musikanth	16 Dec 2020 23:37:20
DataPoint set to visible.	(b) (4) System	16 Dec 2020 23:36:09

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '97.9' F	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '74'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User entered 'bpm'	System	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '18'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User entered 'breaths/min'	System	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '144'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User entered 'mmHg'	System	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '82'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User entered 'mmHg'	System	16 Dec 2020 23:37:20

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47

US3112113

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47

US3112113

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:30

US3112113

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14 Dec 2020'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:30

US3112113

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:09:10

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:40

US3112113

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:09:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:17:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14 Dec 2020'	Matthew Musikanth (b) (4)	16 Dec 2020 23:37:40

US3112113

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

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Natalie Moy (b) (4)	26 Jan 2021 17:48:27

US3112113

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

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '22 Jan 2021'	Natalie Moy (b) (4)	26 Jan 2021 17:48:27

US3112113

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

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	26 Jan 2021 17:48:27

US3112113

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

Form: Visit Date

Generated On: 09 Jun 2021 15:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 17:48:27

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '22 Jan 2021'	Natalie Moy (b) (4)	26 Jan 2021 17:48:46

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	26 Mar 2021 18:26:14
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:36:43

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Natalie Moy (b) (4)	26 Jan 2021 17:48:46

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Amendment 6 or later (Amendment 6 or later)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:26:14
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:36:43

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '22 Jan 2021'	Natalie Moy (b) (4)	26 Jan 2021 17:48:46

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Moy (b) (4)	26 Jan 2021 17:48:46

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Moy (b) (4)	26 Jan 2021 17:48:46

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Moy (b) (4)	26 Jan 2021 17:48:46

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	26 Jan 2021 17:48:46

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User entered empty.	System	26 Jan 2021 17:48:46

US3112113

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:10

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User entered empty.	System	26 Jan 2021 17:48:46

US3112113

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Natalie Moy (b) (4)	26 Jan 2021 17:49:01

US3112113

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '22 Jan 2021'	Natalie Moy (b) (4)	26 Jan 2021 17:49:01

US3112113

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14:10'	Natalie Moy (b) (4)	26 Jan 2021 17:49:01

US3112113

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:10

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User entered '22 Jan 2021 14:10'	System	26 Jan 2021 17:49:01

US3112113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Natalie Moy (b) (4)	26 Jan 2021 17:49:10

US3112113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:09:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '22 Jan 2021'	Natalie Moy (b) (4)	26 Jan 2021 17:49:10

US3112113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '14:06'	Natalie Moy (b) (4)	26 Jan 2021 17:49:10

US3112113

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:09:10

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:23:25
User entered '22 Jan 2021 14:06'	System	26 Jan 2021 17:49:10

US3112113

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:09:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:51
User closed query 'Per DM CLR: Medical Attention was checked for DAY 23 on Diary Dose 1. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. Otherwise, clarify what is the reason for the Medical Attention. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 04:38:06
Query 'Per DM CLR: Medical Attention was checked for DAY 23 on Diary Dose 1. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. Otherwise, clarify what is the reason for the Medical Attention. ' answered with 'Please note that eDiary survey question is posited as follows "Did you receive ANY medical attention (doctor visit, other) for ANY illness or symptoms?" Patient reported receipt of medical attention pertaining to other already reported adverse event unrelated to vaccine or study procedures. Please see MAAE term; "Right shoulder pain" (Site from DM).	Matthew Musikanth (b) (4)	20 Apr 2021 20:29:34
User opened query 'Per DM CLR: Medical Attention was checked for DAY 23 on Diary Dose 1. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. Otherwise, clarify what is the reason for the Medical Attention. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 22:34:58

US3112113

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:09:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:53:01
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 29). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:05:51
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 29). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated ' (Site from DM).	Brenda Grande (b) (4)	09 Feb 2021 17:39:01
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 29). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 11:30:42
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:47:14

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
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: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:48:51
Data point term sent to Coder	System	26 Aug 2020 16:49:05
User entered 'Right Shoulder pain'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 06:43:10
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	02 Sep 2020 20:53:48
User entered '19 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User entered empty.	System	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 19:39:29
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	17 Dec 2020 18:59:46
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	17 Dec 2020 18:59:40
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:51:42
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Dec 2020 19:03:05
User entered '01 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	17 Dec 2020 19:03:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Dec 2020 18:59:40
User entered 'un Sep 2020' (non-conformant).	Matthew Musikanth (b) (4)	17 Dec 2020 18:59:40
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User entered empty.	System	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:34:18
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'updated ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	18 Nov 2020 21:10:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	18 Nov 2020 21:10:31
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:59:38
User entered 'Not Applicable (NOT APPLICABLE)'	Karen Mylerberg (b) (4) (b) (4)	26 Aug 2020 16:48:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'None (NONE)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'I'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	17 Dec 2020 18:59:40
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 16:49:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 16:49:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	26 Aug 2020 16:49:01
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 16:48:45
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User entered '0'	System	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46
User entered 'I'	System	26 Aug 2020 16:48:45

US3112113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:13:04
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:46

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 20:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 20:41:45
Data point term sent to Coder	System	15 Oct 2020 20:34:44
User entered 'diarrhea'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '16 Sep 2020'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
User entered empty.	System	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '16 Sep 2020'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
User entered empty.	System	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'None (NONE)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'I'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
User entered '0'	System	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19
User entered 'I'	System	15 Oct 2020 20:34:18

US3112113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:59
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:19

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of LEFT KNEE OSTEOARTHRITIS noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 19:39:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 19:08:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	17 Dec 2020 19:08:50
Data point term sent to Coder	System	17 Dec 2020 19:07:46
Query 'Per DM CLR: Please confirm if this AE is a worsening of LEFT KNEE OSTEOARTHRITIS noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'Updated' (Site from DM).	Matthew Musikanth (b) (4)	17 Dec 2020 19:07:36
Coding entries removed.	Matthew Musikanth (b) (4)	17 Dec 2020 19:07:30
User entered 'worsening of LEFT KNEE OSTEOARTHRITIS' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	17 Dec 2020 19:07:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of LEFT KNEE OSTEOARTHRITIS noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:24:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 22:17:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 22:17:50
Data point term sent to Coder	System	17 Nov 2020 21:36:48
User closed query 'CDM Coding: Please specify the underlying medical condition for this procedure.' (Site from System).	System	17 Nov 2020 21:35:58
Query 'CDM Coding: Please specify the underlying medical condition for this procedure.' answered with 'updated, as per source. additionally in the narrative.' (Site from System).	Natalie Moy (b) (4)	17 Nov 2020 21:35:58
Data point term sent to Coder	System	17 Nov 2020 21:35:47
User entered 'KNEE JOINT ASPIRATION due to osteoarthritis' reason for change: Data Entry Error	Natalie Moy (b) (4)	17 Nov 2020 21:35:36
User opened query 'CDM Coding: Please specify the underlying medical condition for this procedure.' (Site from System).	Coder Import (b) (4)	12 Nov 2020 03:52:40
Data point term sent to Coder	System	10 Nov 2020 23:49:01
User entered 'knee joint aspiration'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '10 Nov 2020'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
User entered empty.	System	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Nov 2020 23:48:48
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Nov 2020 23:48:48
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Nov 2020 23:48:26
User entered '10 Nov 2020'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
User entered empty.	System	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

Severity

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 15:04:18
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' answered with 'per PI severity has been updated to grade 2 ' (Site from DM).	Brenda Grande (b) (4)	07 Jan 2021 21:52:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Brenda Grande (b) (4)	07 Jan 2021 21:51:37
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 12:29:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:33:50
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Natalie Moy (b) (4)	18 Nov 2020 21:09:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Natalie Moy (b) (4)	18 Nov 2020 21:09:11
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:05:29
User entered 'Not Applicable (NOT APPLICABLE)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Natalie Moy (b) (4)	18 Nov 2020 21:09:11
User entered 'Not Applicable (NOT APPLICABLE)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'None (NONE)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'I'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'I'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Natalie Moy (b) (4)	10 Nov 2020 23:48:48
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'SUBJECT HAD A KNEE JOINT ASPIRATION SUDDENLY DUE TO FLUID BUILDUP FROM OSTEOARTHRITIS. TOOK A SHOT OF CORTISONE. NO ADDITIONAL MEDICATIONS.' reason for change: Data Entry Error	Natalie Moy (b) (4)	10 Nov 2020 23:48:48
User entered 'subject had a knee joint aspiration suddely due to fluid buildup from osteoarthritis. Took a shot of cortisone. no additional medications.'	Natalie Moy (b) (4)	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
User entered '0'	System	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08
User entered 'I'	System	10 Nov 2020 23:48:26

US3112113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:48
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:08

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 00:02:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 00:02:52
Data point term sent to Coder	System	23 Dec 2020 00:02:12
User entered 'uri'	Matthew Musikanth	23 Dec 2020 00:01:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '09 Dec 2020'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
User entered empty.	System	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '21 Dec 2020'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
User entered empty.	System	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Dec 2020 00:01:33
User entered '1' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:33
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Dec 2020 00:01:28
User entered '0'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
User entered '0'	System	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59
User entered 'I'	System	23 Dec 2020 00:01:28

US3112113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:44
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:59

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast disorders NEC, PT: Breast ulceration, LLT: Breast ulceration - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 16:02:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 16:02:41
Data point term sent to Coder	System	31 Dec 2020 00:30:45
User entered 'Left Breast Sore'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '27 Dec 2020'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'l'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:09:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Dec 2020 00:30:22

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: UTI - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 20:55:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 20:55:23
Data point term sent to Coder	System	29 Jan 2021 20:54:52
User entered 'UTI'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '26 Jan 2021'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'l'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:09:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 20:54:34

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 17:41:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 17:41:34
Data point term sent to Coder	System	09 Feb 2021 17:40:38
User entered 'fatigue'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '06 Aug 2020'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 23:46:48
Query 'Data is required. Please provide.' answered with 'time unk' (Site from System).	Brenda Grande (b) (4)	09 Feb 2021 17:40:23
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 17:40:15
User entered empty.	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
User entered empty.	System	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '02 Sep 2020'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 23:46:51
Query 'Data is required. Please provide.' answered with 'time unk' (Site from System).	Brenda Grande (b) (4)	09 Feb 2021 17:40:28
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 17:40:15
User entered empty.	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
User entered empty.	System	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Related (RELATED)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'None (NONE)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'I'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Brenda Grande (b) (4)	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
User entered '0'	System	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18
User entered '0'	System	09 Feb 2021 17:40:15

US3112113

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 16:12:37
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:12:18

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle injury, LLT: Hamstring injury - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 01:04:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 01:04:47
Data point term sent to Coder	System	26 Feb 2021 21:45:14
User entered 'Right Hamstring Injury'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '25 Feb 2021'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

Death

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 19:09:44
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	16 Mar 2021 17:00:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:12:25
User entered 'I'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:09:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 21:44:16

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:06
User entered 'USA-US062-2021-mRNA-1273-P301000014'	(b) (4), (b) (6)	29 Apr 2021 13:15:59

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Haematuria, LLT: Hematuria - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 17:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 17:26:28
Data point term sent to Coder	System	06 Apr 2021 17:25:17
Coding entries removed.	Matthew Musikanth	06 Apr 2021 17:24:59
Signature has been broken.	(b) (4)	
	Matthew Musikanth	06 Apr 2021 17:24:59
User entered 'Intermittent HEMATURIA' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Matthew Musikanth	06 Apr 2021 17:24:59
	(b) (4)	
	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Haematuria, LLT: Hematuria - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 15:35:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 15:35:44
User closed query 'DM-Coding: please split this term into 2 separate entries. One record per line. Please update this term in accordance with your answer.' (Site from System).	System	17 Mar 2021 15:35:33
Query 'DM-Coding: please split this term into 2 separate entries. One record per line. Please update this term in accordance with your answer.' answered with 'updated' (Site from System).	Brenda Grande (b) (4)	17 Mar 2021 15:35:33
User entered 'HEMATURIA' reason for change: Data Entry Error	(b) (4)	
User opened query 'DM-Coding: please split this term into 2 separate entries. One record per line. Please update this term in accordance with your answer.' (Site from System).	Brenda Grande (b) (4)	17 Mar 2021 15:35:19
Data point term sent to Coder	Coder Import (b) (4)	17 Mar 2021 10:10:42
	(b) (4)	
	System	03 Mar 2021 22:20:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Hematuria with thrombosis'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '02 Mar 2021'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
Signature has been broken.	Matthew Musikanth	06 Apr 2021 17:24:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	06 Apr 2021 17:24:59
User signature succeeded.	Matthew Musikanth	06 Apr 2021 17:24:59
	(b) (4)	
	Todd Simmons	19 Mar 2021 20:20:12
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
Signature has been broken.	Matthew Musikanth	06 Apr 2021 17:24:59
User entered empty; reason for change Data Entry Error	(b) (4)	06 Apr 2021 17:24:59
User signature succeeded.	Matthew Musikanth	06 Apr 2021 17:24:59
	(b) (4)	
	Todd Simmons	(b) (4) 19 Mar 2021 20:20:12
User entered '02 Mar 2021'	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
Signature has been broken.	Matthew Musikanth	28 Apr 2021 21:59:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	28 Apr 2021 21:59:09
DataPoint Un-verified.	Matthew Musikanth	28 Apr 2021 21:59:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'No (N)'	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
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).		28 Apr 2021 22:00:16
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 by data change (Site from System).		28 Apr 2021 22:00:16
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	28 Apr 2021 21:59:09
Signature has been broken.	Matthew Musikanth	28 Apr 2021 21:59:09
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Matthew Musikanth	28 Apr 2021 21:59:09
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
Signature has been broken.	Matthew Musikanth	28 Apr 2021 21:59:09
User entered '23 Apr 2021' reason for change: Data Entry Error	(b) (4)	28 Apr 2021 21:59:09
DataPoint Un-verified.	Matthew Musikanth	28 Apr 2021 21:59:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
Signature has been broken.	Matthew Musikanth	28 Apr 2021 21:59:09
User entered '24 Apr 2021' reason for change: Data Entry Error	(b) (4)	28 Apr 2021 21:59:09
DataPoint Un-verified.	Matthew Musikanth	28 Apr 2021 21:59:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
Signature has been broken.	Matthew Musikanth	28 Apr 2021 22:00:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Apr 2021 22:00:16
DataPoint Un-verified.	Matthew Musikanth	28 Apr 2021 22:00:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). Signature has been broken.	Matthew Musikanth	28 Apr 2021 22:00:27
User entered '0' reason for change: Data Entry Error	(b) (4)	28 Apr 2021 22:00:27
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). DataPoint Un-verified.	Matthew Musikanth	28 Apr 2021 21:59:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '1'	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered '0'	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
Signature has been broken.	Matthew Musikanth	28 Apr 2021 21:59:09
User entered '1' reason for change: Data Entry Error	(b) (4)	28 Apr 2021 21:59:09
DataPoint Un-verified.	Matthew Musikanth	28 Apr 2021 21:59:09
DataPoint Verified.	(b) (4)	07 Apr 2021 16:53:22
User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User entered '0'	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
Signature has been broken.	Matthew Musikanth	06 Apr 2021 17:24:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Matthew Musikanth	06 Apr 2021 17:24:59
	(b) (4)	
	Todd Simmons	(b) (4) 19 Mar 2021 20:20:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth (b) (4)	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:06
Signature has been broken.	Matthew Musikanth	28 Apr 2021 22:00:16
User entered 'PATIENT SEEN ON 23APR2021 for overnight stay in hospital due to cystoscopy and bulking procedure for existing AE.' reason for change: Data Entry Error	(b) (4)	28 Apr 2021 22:00:16
DataPoint Un-verified.	Matthew Musikanth	28 Apr 2021 22:00:16
	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:53:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:20:12
User entered empty.	Matthew Musikanth	03 Mar 2021 22:19:45
	(b) (4)	

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 21:59:09
User entered '0'	System	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 22:19:45

US3112113

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 22:00:16

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:39:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:53:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered	System	29 Mar 2021 16:00:45
'USA-US062-2021-mRNA-1273-P301000014'	(b) (4), (b) (6)	29 Mar 2021 16:00:45
User entered 'New'		

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Rupture tendon - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 07:45:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 07:45:26
Data point term sent to Coder	System	06 Apr 2021 16:57:26
DataPoint Un-verified.	Matthew Musikanth	06 Apr 2021 16:57:09
Coding entries removed.	(b) (4)	06 Apr 2021 16:57:09
Signature has been broken.	Matthew Musikanth	06 Apr 2021 16:57:09
User entered 'Full thickness tear of supraspinatus tendon' reason for change: Data Entry Error	Matthew Musikanth	06 Apr 2021 16:57:09
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:53:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
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: Pain in extremity, LLT: Painful L arm - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 18:24:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 18:24:27
Data point term sent to Coder	System	26 Mar 2021 18:23:44
User entered 'Left Arm Pain'	Matthew Musikanth	26 Mar 2021 18:23:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:53:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:53:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:53:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:53:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '23 Mar 2021'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:38:56
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'will updated when available.' (Site from Safety).	Matthew Musikanth (b) (4)	06 Apr 2021 16:55:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:54:02
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:18:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:54:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:54:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:54:33
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 08:07:44
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 'Pending, patient is still admitted.' (Site from System).	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:36
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	26 Mar 2021 18:23:19
User entered 'I'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:54:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '25 Mar 2021'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:51:40
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:39:08
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	06 Apr 2021 16:55:47
Signature has been broken.	Matthew Musikanth (b) (4)	06 Apr 2021 16:54:34
User entered '27 Mar 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	06 Apr 2021 16:54:34
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:19:41
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:18:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:54:41
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 22:06:11
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	09 Apr 2021 16:35:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:39:28
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment given at this time. Will update.' (Site from Safety).	Matthew Musikanth (b) (4)	06 Apr 2021 16:56:20

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:19:04
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 03:04:36
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'I'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:18:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:52:04
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:19:22
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:17:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'patient reports onset of pain on 23Mar2021, pain climaxed on 25Mar2021 leading to hospital visit. Patient spend the night at hospital and is still admitted at time of initial report.'	Matthew Musikanth (b) (4)	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 18:23:19

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLG: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:25:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:25:42
Data point term sent to Coder	System	19 Apr 2021 21:25:02
User entered 'Left ovarian Cyst'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Apr 2021'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
User entered 'I'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:09:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 21:24:59

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Adverse event](#)

Audit	User	Time (GMT)
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)	28 Apr 2021 22:02:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 22:02:27
Data point term sent to Coder	System	28 Apr 2021 22:01:27
User entered 'Hypertension'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Apr 2021'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

None

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Matthew Musikanth (b) (4)	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 22:01:14

US3112113

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:09:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 22:01:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'no medications reported per day 8 phone call' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 18:53:17
	Natalie Moy (b) (4)	26 Jan 2021 17:47:39
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 12:01:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:26:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: DESMOPRESSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 09:53:09
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 09:53:09
Data point term sent to Coder	System	20 Aug 2020 15:28:02
User entered 'Desmopressin'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Overactive Bladder'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
	(b) (4), (b) (6)	22 Oct 2020 18:22:41
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	Natalie Moy (b) (4)	12 Oct 2020 18:19:59
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4)	12 Oct 2020 18:19:52
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	14 Sep 2020 23:05:11
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 15:27:29
User entered 'mg (mg)'	(b) (4), (b) (6)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:21:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:27:29
User entered 'UN UNK 2017'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 15:27:29

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
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
	(b) (4)	
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
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 15:29:05
User entered 'Gabapentin'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:42:59
Query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	30 Sep 2020 10:42:50
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 18:36:27
User opened query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	16 Sep 2020 18:33:30
' (Site from DM).		
User entered 'Chronic Pain'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '900'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:21:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:28:09
User entered 'UN UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 15:28:09

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:16:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:16:25
Data point term sent to Coder	System	20 Aug 2020 15:29:06
User entered 'Celebrex'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:49:59
User opened query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:20:45
User entered 'Chronic Pain'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '200'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:21:45
User entered 'UN UNK 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:35:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:28:52
User entered 'UN Dec 2015'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 15:28:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 11:05:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 11:05:55
Data point term sent to Coder	System	20 Aug 2020 15:31:08
User entered 'Lyrica'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Query 'Per DM CLR: Please update the indication to reflect the location of NEURALGIA/CHRONIC PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:50:10
User opened query 'Per DM CLR: Please update the indication to reflect the location of NEURALGIA/CHRONIC PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:22:02
User entered 'Neuralgia/Chronic Pain'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '75' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	31 Mar 2021 21:06:40
User entered '100'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:21:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:30:22
User entered 'UN Jun 2020'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 15:30:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 15:32:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 15:32:26
Data point term sent to Coder	System	20 Aug 2020 15:31:10
User entered 'Colace'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Constipation'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '100'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:21:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:31:08
User entered 'UN UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 15:31:08

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUNISOLIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 00:36:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 00:36:34
Data point term sent to Coder	System	20 Aug 2020 15:33:17
User entered 'Flunisolide Nasal Solution'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Allergies'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Spray'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:21:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:33:00
User entered 'UN UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	26 Aug 2020 16:49:41
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		26 Aug 2020 16:49:41
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		20 Aug 2020 15:33:00
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 15:33:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OTHER DRUGS FOR CONSTIPATION, PRODUCT: LINACLOTIDE, PRODUCTSYNONYM: LINZESS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 15:35:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 15:35:21
Data point term sent to Coder	System	20 Aug 2020 15:34:19
User entered 'Linzess'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Constipation'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:23:21
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 18:20:59
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:27:29
User entered '75'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:23:23
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Natalie Moy (b) (4)	12 Oct 2020 18:21:05
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 18:20:46
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:27:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:21:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:33:49
User entered 'UN UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 15:33:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 15:36:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 15:36:18
Data point term sent to Coder	System	20 Aug 2020 15:35:21
User entered 'Albuterol'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Asthma'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '90'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mcg/inhalation'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:21:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:34:54
User entered 'UN UNK 1978'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 15:34:54

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:13:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:13:34
Data point term sent to Coder	System	12 Oct 2020 18:22:57
Coding entries removed.	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 18:22:23
User entered 'VOLTAREN TOPICAL GEL 1%' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	12 Oct 2020 18:22:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:11:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:11:33
Data point term sent to Coder	System	26 Aug 2020 16:52:19
User entered 'Voltaren topical gel'	Karen Mylerberg (b) (4) (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Query 'Per DM CLR: Note, 1% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, Dose = 1; Dose Unit = Other ; Specify = Application). Update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 05:06:52
User opened query 'Per DM CLR: Note, 1% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, Dose = 1; Dose Unit = Other ; Specify = Application). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 05:06:44
User entered 'Right Shoulder pain'	Karen Mylerberg (b) (4) (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Per DM CLR: Note, 1% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, Dose = 1; Dose Unit = Other ; Specify = Application). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:23:43
Query 'Per DM CLR: Note, 1% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, Dose = 1; Dose Unit = Other ; Specify = Application). Update as appropriate. ' answered with 'updated' (Site from DM).	Natalie Moy (b) (4)	12 Oct 2020 18:22:32
User opened query 'Per DM CLR: Note, 1% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, Dose = 1; Dose Unit = Other ; Specify = Application). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:25:12
Query 'Per DM CLR: Note, 1% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, Dose = 1; Dose Unit = Other ; Specify = Application). Update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 05:07:32
User opened query 'Per DM CLR: Note, 1% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, Dose = 1; Dose Unit = Other ; Specify = Application). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 05:06:57
User entered 'I'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Other (OTHER)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'layer' reason for change: Data Entry Error	Natalie Moy (b) (4)	12 Oct 2020 18:22:23
User entered 'percent'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'once daily (QD)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Topical (TOPICAL)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '25 Aug 2020'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 04:14:08
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4)	11 Jan 2021 17:01:38
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4)	11 Jan 2021 17:01:23
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 12:29:36
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '01 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4)	11 Jan 2021 17:01:23
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Karen Mylerberg (b) (4)	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User entered '1'	System	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User entered '1'	System	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:28
User entered '804 (804)'	System	26 Aug 2020 16:52:17

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 05:14:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 05:14:20
Data point term sent to Coder	System	15 Oct 2020 20:30:34
User entered 'Tramadol'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'right shoulder pain'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'unknown'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Other (OTHER)'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'unknown'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'unknown (UNKNOWN)'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '25 Aug 2020'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 04:14:27
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4)	11 Jan 2021 17:04:38
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4)	11 Jan 2021 17:04:28
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 12:29:45
User entered 'Yes (Y)'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Jan 2021 17:04:28
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Jan 2021 17:04:24
User entered '01 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4)	11 Jan 2021 17:04:24
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User entered empty.	System	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User entered empty.	System	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:45
User entered empty.	System	15 Oct 2020 20:30:07

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE, PRODUCTSYNONYM: HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 20:37:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 20:37:47
Data point term sent to Coder	System	15 Oct 2020 20:31:38
User entered 'HCTZ'	Natalie Moy (b) (4) (b) (4)	15 Oct 2020 20:31:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 20:31:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 20:31:11
User entered 'No (N)' reason for change: Data Entry Error	Natalie Moy (b) (4)	15 Oct 2020 20:31:11
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 20:31:00
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:31:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Left knee edema'	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '12.5'	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mg (mg)'	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'once daily (QD)'	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '18 Aug 2020'	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:31:00
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 20:31:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 20:31:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 20:31:00

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ADSORBENTS, ATC: BISMUTH PREPARATIONS, PRODUCT: BISMUTH SUBSALICYLATE, PRODUCTSYNONYM: PEPTO-BISMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 12:16:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 12:16:27
Data point term sent to Coder	System	15 Oct 2020 20:33:40
User entered 'Pepto Bismo'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'diarrhea'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '15'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mL (mL)'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'as needed (PRN)'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '16 Sep 2020'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '17 Sep 2020'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User entered empty.	System	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User entered empty.	System	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:40
User entered empty.	System	15 Oct 2020 20:32:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:00:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:00:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:18:10
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 Nov 2020 10:18:10
Data point term sent to Coder	System	10 Nov 2020 23:47:00
User entered 'cortisone shot'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'osteoarthritis/knee joint aspiration'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'I'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Other (OTHER)'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'shot'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'once (ONCE)'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Other (OTHER)'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'intra-articular'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '10 Nov 2020'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '10 Nov 2020'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Natalie Moy (b) (4)	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User entered empty.	System	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User entered empty.	System	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:35
User entered empty.	System	10 Nov 2020 23:46:41

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: MUPIROCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Dec 2020 00:34:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Dec 2020 00:34:28
Data point term sent to Coder	System	31 Dec 2020 00:31:46
User entered 'Mupirocin'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Left Breast Sore'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '2'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '%'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'three times daily (TID)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Topical (TOPICAL)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '27 Dec 2020'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Dec 2020 00:31:12

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 20:56:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 20:56:24
Data point term sent to Coder	System	29 Jan 2021 20:55:53
User entered 'Macrobid'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'UTI'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '100'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '29 Jan 2021'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Matthew Musikanth (b) (4)	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jan 2021 20:55:14

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:55:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:55:43
Data point term sent to Coder	System	16 Mar 2021 16:56:39
User entered 'tramadol'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'r hamstring injury'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'unk'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Other (OTHER)'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'unknown'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'as needed (PRN)'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '25 Feb 2021'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	16 Mar 2021 16:56:11
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 16:56:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 16:56:15
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4)	16 Mar 2021 16:56:15
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 16:56:11
User entered empty.	Brenda Grande (b) (4)	16 Mar 2021 16:56:11

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:56:11

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:56:11

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:56:11

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACROBID [NITROFURANTOIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 16:59:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 16:59:52
Data point term sent to Coder	System	16 Mar 2021 16:58:44
User entered 'macrobid'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'UTI'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '100'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'mg (mg)'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'once daily (QD)'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Oral (ORAL)'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '17 Feb 2021'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '0'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '21 Feb 2021'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'No (N)'	Brenda Grande (b) (4)	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User entered '1'	System	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User entered '1'	System	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:48:54
User entered '804 (804)'	System	16 Mar 2021 16:58:25

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:33:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:33:40
	(b) (4)	
Data point term sent to Coder	System	07 Apr 2021 17:50:49
User entered 'hydrocodone'	Matthew Musikanth	07 Apr 2021 17:50:39
	(b) (4)	

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'full thickness tear of supraspinatus tendon'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '10-325'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '27 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '0'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:50:39

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:52:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:52:43
Data point term sent to Coder	System	07 Apr 2021 17:51:51
User entered 'keflex'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'recurrent UTI's'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '250'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'qhs'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '28 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '0'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:51:22

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 09:31:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 09:31:08
Data point term sent to Coder	System	07 Apr 2021 17:52:52
User entered 'pantoprazole'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'GI prophylaxis'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '40'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '27 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '0'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 17:51:58

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:54:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:54:45
Data point term sent to Coder	System	07 Apr 2021 17:53:52
User entered 'Robaxin'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Right hamstring injury'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '750'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'three times daily (TID)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '30 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '0'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 17:52:55

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 10:03:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 10:03:52
Data point term sent to Coder	System	07 Apr 2021 17:53:53
User entered 'tramadol'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'full thickness tear of supraspinatus tendon'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '50'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'q12hrs'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '27 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '0'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:53:52

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:55:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:55:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:55:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:55:35
Data point term sent to Coder	System	07 Apr 2021 17:54:53
User entered 'Tylenol'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'full thickness tear of supraspinatus tendon'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '325'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '30 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '0'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 17:54:36

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:19:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:19:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:16:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:16:56
Data point term sent to Coder	System	07 Apr 2021 18:01:07
User entered 'docusate sodium'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'constipation secondary to hospital medications (full thickness tear of supraspinatus tendon)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '100'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '27 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '0'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:00:15

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 18:02:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 18:02:40
Data point term sent to Coder	System	07 Apr 2021 18:01:07
User entered 'Magnesium oxide'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Supplement'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '250'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '27 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '0'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 18:00:46

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 08:27:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 08:27:50
Data point term sent to Coder	System	07 Apr 2021 18:02:08
User entered 'Miralax Packet 17 GM'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'constipation secondary to hospital medications (full thickness tear of supraspinatus tendon)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '1'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'packet'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '27 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered '0'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
User entered 'No (N)'	Matthew Musikanth (b) (4)	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:01:49

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:09:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:51
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:03:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Yes (Y)'	Natalie Moy (b) (4)	10 Nov 2020 23:51:22

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:09:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:47:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '10 Nov 2020'	Natalie Moy (b) (4)	10 Nov 2020 23:51:40

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:47:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Knee Joint aspiration'	Natalie Moy (b) (4)	10 Nov 2020 23:51:40

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:47:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'Adverse Event (AE)'	Natalie Moy (b) (4)	10 Nov 2020 23:51:40

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:09:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:47:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered empty.	Natalie Moy (b) (4)	10 Nov 2020 23:51:40

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:09:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	30 Apr 2021 17:54:57
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:04:15
User entered '23 Apr 2021'	Matthew Musikanth	29 Apr 2021 22:52:30
	(b) (4)	

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	30 Apr 2021 17:54:57
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:04:15
User entered 'cystoscopy and bulking'	Matthew Musikanth	29 Apr 2021 22:52:30
	(b) (4)	

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:09:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	30 Apr 2021 17:54:57
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:04:15
User entered 'Adverse Event (AE)'	Matthew Musikanth	29 Apr 2021 22:52:30
	(b) (4)	

US3112113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:09:10

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	30 Apr 2021 17:54:57
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 23:04:15
User entered empty.	Matthew Musikanth	29 Apr 2021 22:52:30
	(b) (4)	

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:12
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'USA-US062-2021-MRNA-1273-P301000014'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Yes (Y)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Yes (Y)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered 'Todd' reason for change: Data Entry Error	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered (b) (6)	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Todd'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered 'SIMMONS' reason for change: Data Entry Error	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered (b) (6)	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Simmons'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered '9040 FRIARS ROAD suite 540'	Matthew Musikanth	29 Apr 2021 17:46:01
reason for change: Data Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered '9040 Friars Road'	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered '9040 Friars Road Suite 540'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'San Diego'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'CA'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered '92108'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:02
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'US'	System	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 13:17:23
User entered '2'	System	07 Apr 2021 16:40:26
User entered '1'	System	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:12
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'USA-US062-2021-MRNA-1273-P301000014'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Yes (Y)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Yes (Y)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered 'Todd' reason for change: Data Entry Error	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered (b) (6)	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Todd'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered 'SIMMONS' reason for change: Data Entry Error	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered (b) (6)	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Simmons'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered '9040 FRIARS ROAD suite 540'	Matthew Musikanth	29 Apr 2021 17:46:01
reason for change: Data Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered '9040 Friars Road'	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered '9040 Friars Road Suite 540'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'San Diego'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'CA'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered '92108'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:02
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'US'	System	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 13:17:23
User entered '2'	System	07 Apr 2021 16:40:26
User entered '1'	System	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:09:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered '29/Mar/2021 12:01'	System	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:09:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:02
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:12
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'USA-US062-2021-MRNA-1273-P301000014'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Yes (Y)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Yes (Y)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE-USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered 'Todd' reason for change: Data Entry Error	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered (b) (6)	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Todd'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered 'SIMMONS' reason for change: Data Entry Error	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered (b) (6)	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Simmons'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered '9040 FRIARS ROAD suite 540'	Matthew Musikanth	29 Apr 2021 17:46:01
reason for change: Data Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered '9040 Friars Road'	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered '9040 Friars Road Suite 540'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'San Diego'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'CA'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered '92108'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:02
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'US'	System	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 13:17:23
User entered '2'	System	07 Apr 2021 16:40:26
User entered '1'	System	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:09:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:43:02
User entered '07/Apr/2021 12:40'	System	07 Apr 2021 16:40:26

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:09:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:48:33
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:43:02
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 16:40:26

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:12
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'USA-US062-2021-MRNA-1273-P301000014'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Yes (Y)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Yes (Y)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'No (N)'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered 'Todd' reason for change: Data Entry Error	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered (b) (6)	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Todd'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered 'SIMMONS' reason for change: Data Entry Error	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered (b) (6)	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'Simmons'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
Un-reviewed for Safety.	Matthew Musikanth	29 Apr 2021 17:46:01
	(b) (4)	
User entered '9040 FRIARS ROAD suite 540'	Matthew Musikanth	29 Apr 2021 17:46:01
reason for change: Data Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:16:52
Un-reviewed for Safety.	System	29 Apr 2021 13:15:59
DataPoint Un-verified.	System	29 Apr 2021 13:15:59
Signature has been broken.	System	29 Apr 2021 13:15:59
User entered '9040 Friars Road'	System	29 Apr 2021 13:15:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered '9040 Friars Road Suite 540'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'San Diego'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered 'CA'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:00:56
User entered '92108'	System	29 Mar 2021 16:00:45

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 16:40:02
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:52:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:59:07
User entered 'US'	System	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 13:17:23
User entered '2'	System	07 Apr 2021 16:40:26
User entered '1'	System	29 Mar 2021 16:01:05

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:09:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
User entered '29/Apr/2021 06:17'	System	29 Apr 2021 13:17:23

US3112113

Folder: SAE USA-US062-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:09:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	29 Apr 2021 19:04:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 19:00:07
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 13:17:23
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 13:17:05