

US3112043 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:13:17

All time stamps listed in this document are displayed in GMT

US3112043

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Participant ID

US3112043

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

US3112043

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:38:45

Generated On: 09 Jun 2021 15:13:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3112043

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:38:44

Generated On: 09 Jun 2021 15:13:17

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:38:44

Generated On: 09 Jun 2021 15:13:17

Date of Informed Consent (*dd MMM yyyy*) 31 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:38:44

Generated On: 09 Jun 2021 15:13:17

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 16:38:45

Generated On: 09 Jun 2021 15:13:17

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Condition	BILATERAL LOWER EXTREMITY PEDAL EDEMA
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)	

US3112043

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Condition	TINEA CORPORIS
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3112043

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3112043

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

US3112043

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Condition	GOUT (PRIMARILY RIGHT BIG TOE)
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3112043

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	
Start date completely unknown	True
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 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

US3112043

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Condition	BILATERAL CATARACT SURGERY
Start date (dd MMM yyyy)	UN JAN 2020
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 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

US3112043

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:38:45

Generated On: 09 Jun 2021 15:13:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	08:55 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 08:55
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	254.6 lb
BMI (<i>xxx.x</i>)	39.95937 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 16:38:45

Generated On: 09 Jun 2021 15:13:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 2020

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

US3112043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:38:45

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify REALTOR

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 16:38:45

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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)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 184250

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Height	ND - Not Done
Weight	ND - Not Done

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

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)	31 JUL 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 08:55
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)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

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)	31 JUL 2020
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 11:19
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)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	086 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

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) 31 JUL 2020

What was the treatment time? (00:00-23:59) 10:48 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 10:48

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 20:38:17

Generated On: 09 Jun 2021 15:13:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 JUL 2020
Collection time (00:00-23:59)	09:26 (24 HR)
Collection date and time (derived)	31 JUL 2020 09:26

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Collection date (dd MMM yyyy)			31 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:26	31 JUL 2020 09:26
Nasopharyngeal Swab 2	No		

US3112043

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 11:23

PC Open Date & Time

31 JUL 2020 11:08

PC Close Date & Time

31 JUL 2020 13:38

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	31 JUL 2020 18:31
PC Open Date & Time	31 JUL 2020 14:33
PC Close Date & Time	01 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 12:38

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 00:10

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 00:20

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 15:33

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

97.5 °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

06 AUG 2020 00:39

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

97.5 °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

06 AUG 2020 18:54

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

31 JUL 2020 11:24

PC Open Date & Time

31 JUL 2020 11:08

PC Close Date & Time

31 JUL 2020 13:38

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

31 JUL 2020 18:32

PC Open Date & Time

31 JUL 2020 14:33

PC Close Date & Time

01 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

01 AUG 2020 12:39

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

03 AUG 2020 00:11

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

04 AUG 2020 00:20

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

04 AUG 2020 15:33

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

06 AUG 2020 00:39

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

06 AUG 2020 18:54

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 11:25
PC Open Date & Time	31 JUL 2020 11:08
PC Close Date & Time	31 JUL 2020 13:38

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 18:34
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PC Open Date & Time	31 JUL 2020 14:33
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PC Close Date & Time	01 AUG 2020 11:59
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US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 12:40
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

53 of 2288

EAB) (1725)

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 00:22
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

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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US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 15:34
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

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EAB) (1725)

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 00:40
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

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 ☒

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 18:55
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3112043

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 8
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	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3112043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:31:37

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:31:37

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:31:37

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:31:37

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:31:37

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:31:37

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

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

Visit date (dd MMM yyyy)	26 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	11:17 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:17
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	056 mmHg
Diastolic Blood Pressure units	MMHG

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

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)	26 AUG 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:16
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3112043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3112043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 AUG 2020

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 12:45

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

US3112043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

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

Collection date (dd MMM yyyy)	26 AUG 2020
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Collection time (00:00-23:59)	11:35 (24 HR)
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Collection date and time (derived)	26 AUG 2020 11:35
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US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:56	26 AUG 2020 11:56
Nasopharyngeal Swab 2	No		

US3112043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 13:54

PC Open Date & Time

26 AUG 2020 13:05

PC Close Date & Time

26 AUG 2020 15:35

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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	26 AUG 2020 20:52
PC Open Date & Time	26 AUG 2020 16:30
PC Close Date & Time	27 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

97.6 °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

27 AUG 2020 16:02

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 15:13

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

30 AUG 2020 22:06

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 21:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 18:12

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

26 AUG 2020 13:55

PC Open Date & Time

26 AUG 2020 13:05

PC Close Date & Time

26 AUG 2020 15:35

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 20:52

PC Open Date & Time

26 AUG 2020 16:30

PC Close Date & Time

27 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 16:03

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 15:13

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

30 AUG 2020 22:06

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 21:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 18:12

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 13:54
PC Open Date & Time	26 AUG 2020 13:05
PC Close Date & Time	26 AUG 2020 15:35

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 20:53
PC Open Date & Time	26 AUG 2020 16:30
PC Close Date & Time	27 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 16:03
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

Yes ☐

PC Time stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

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 ☒

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 15:14
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

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 ☒

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 22:07
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

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 ☒

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 21:14
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

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 ☒

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 18:13
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 SEP 2020 12:02

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3112043

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

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	02 SEP 2020 12:02
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3112043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:31:37

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:31:37

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	9:45 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 9:45
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	55 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

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.

US3112043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:38:17

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Patient Cloud Close Date & Time

04 OCT 2020 23:59

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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"/>

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 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"/>

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	24 DEC 2020 23:59
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US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

28 DEC 2020 16:30:03

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

06 JAN 2021 18:00:40

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 11:29:02
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

17 JAN 2021 09:34:23

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

25 JAN 2021 15:33:27

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

02 FEB 2021 11:52:37

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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	07 FEB 2021 09:51:23
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 00:35:26

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 14:15:11

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

28 FEB 2021 08:26:48

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 20:06:52

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	14 MAR 2021 11:36:00
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 15:52:12

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 17:25:16

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

05 APR 2021 19:57:39

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 16:46:43

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 16:27:43

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

25 APR 2021 18:17:23

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission

02 MAY 2021 22:33:28

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 <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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
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Patient Cloud Close Date & Time	29 JUL 2021 23:59
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US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 446

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

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

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

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

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

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

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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="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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 <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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 670

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

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

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

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

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

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

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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="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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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"/>

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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

Date and time of submission

Patient Cloud Open Date & Time	02 OCT 2022 00:01
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Patient Cloud Close Date & Time	06 OCT 2022 23:59
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US3112043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:13:17

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 17:04:21

US3112043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:40:57

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:40:57

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

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

Visit date (dd MMM yyyy)	22 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	10:24 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 10:24
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	84 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	50 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3112043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 22 FEB 2021

Collection time (00:00-23:59) 10:51 (24 HR)

Collection date and time (derived) 22 FEB 2021 10:51

US3112043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:38:12

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3112043

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112043

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112043

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:13:17

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3112043

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

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

Visit date (dd MMM yyyy)	6 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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US3112043

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Date of updated informed consent (dd MMM yyyy) 6 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) 6 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 _____

US3112043

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

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

Collection date (dd MMM yyyy)	6 JAN 2021
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Collection time (00:00-23:59)	13:55 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	6 JAN 2021 13:55
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US3112043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	13:59
Collection Date and Time (derived)	6 JAN 2021 13:59

US3112043

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:16:53

Generated On: 09 Jun 2021 15:13:17

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

AEID

Adverse event

CERVICAL RADICULOPATHY

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 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)

17 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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

AEID	USA-US062-2021-MRNA-1273-P30 1000012
Adverse event	DIVERTICULITIS WITH SPONTANEOUS RESOLUTION
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 MAR 2021
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)	13 MAR 2021
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)	09 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	13 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	341 of 2288

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

PT. WOKE UP MORNING OF
09MAR2021 AND NOTICED
BLOOD WITH BOWEL
MOVEMENTS. CONTINUED
BLEEDING PROMPTED PATIENT
TO PRESENT AT ED. AFTER
DIAGNOSTICS AT HOSPITAL,
NO CAUSE DETERMINED AND
BLEEDING SPONTANEOUSLY
RESOLVED. PATIENT
DISCHARGE DAY AFTER.
TOTAL OF 4 DAYS SPENT IN
HOSPITAL.

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

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

AEID	
Adverse event	BARRETTS ESOPHAGUS
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)	10 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 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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 21:01:51

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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	
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)

Data signed: (b) (4) 23 Apr 2021 21:01:51

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AEID	
Adverse event	RIGHT KNEE PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	UN 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 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 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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 21:01:51

Generated On: 09 Jun 2021 15:13:17

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	
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 20:37:13

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:37:13

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Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BPH

Dose per administration 0.4

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)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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) _____		
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 (2)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication BILATERAL LOWER
EXTERMITY PEDAL EDEMA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:37:13

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	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)	UN UNK 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication GOUT

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:37:13

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:37:13

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HTN

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 (4)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

	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 1995	
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 (5)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication MINOXIDIL

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

	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 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 FEB 2021	
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 (6)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

	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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HTN

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 (7)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

	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 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 FEB 2021	
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 (8)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication BARRETT'S ESOPHAGUS

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 (8)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

	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)	13 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)	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 (9)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

	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)	2 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication MINOXIDIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

	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)	02 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication STEROID INJECTION

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE PAIN

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

	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	INTRAJOINT	
Start date (dd MMM yyyy)	UN DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	UN DEC 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"/>

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Name of Medication BLOOD TRANSFUSION

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 1

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

If dose unit is Other, specify UNIT

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

	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 checked="" 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)	09 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		09 MAR 2021
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"/>

US3112043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:37:13

Generated On: 09 Jun 2021 15:13:17

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3112043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:13:17

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

US3112043

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:13:17

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 ☐

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 23:34:15

Generated On: 09 Jun 2021 15:13:17

SAEID	USA-US062-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 23:34:15

Generated On: 09 Jun 2021 15:13:17

SAEID	USA-US062-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	16/MAR/2021 09:43
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

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 23:34:15

Generated On: 09 Jun 2021 15:13:17

SAEID	USA-US062-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	19/MAR/2021 09:59
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

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Apr 2021 23:34:15

Generated On: 09 Jun 2021 15:13:17

SAEID	USA-US062-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	19/MAR/2021 11:03
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

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 15 Apr 2021 23:34:15

Generated On: 09 Jun 2021 15:13:17

SAEID	USA-US062-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	29/MAR/2021 11:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 15 Apr 2021 23:34:15

Generated On: 09 Jun 2021 15:13:17

SAEID	USA-US062-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	14/APR/2021 13:48
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

US3112043 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112043

Form: Participant Creation

Generated On: 09 Jun 2021 15:13:17

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 19:26:40
User entered 'US3112043'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:04:28

US3112043

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:00:36
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:10

US3112043

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:00:36
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:04:29

US3112043

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:00:36
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:10

US3112043

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'SCRN'	System	31 Jul 2020 18:11:10

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:04:30

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered '75'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'YEARS'	System	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '75'	System	31 Jul 2020 18:11:19

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered 'Male (M)'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered 'I'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:13:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:04:48
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:13:39

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:05:20
User entered '31 Jul 2020'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:19

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jul 2020'	System	31 Jul 2020 18:11:19

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '2020'	System	31 Jul 2020 18:11:19

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:05:20
User entered 'Amendment 1 (1)'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:19

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:05:20
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:19

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:05:20
User entered empty.	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:19

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:05:20
User entered empty.	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:19

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:05:20
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:26
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:19

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:05:20
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	31 Jul 2020 18:11:26
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	31 Jul 2020 18:11:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:04:29

US3112043

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:13:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'I'	System	31 Jul 2020 18:11:32

US3112043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:13:17

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:05:29
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:32

US3112043

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:13:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:20:33
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) (6)	09 Sep 2020 02:32:37
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 updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:57:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:57:36
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 10:44:49
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:43:13

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:37
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) (b) (4)	06 Sep 2020 20:59:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 20:59:41
Data point term sent to Coder	System	06 Sep 2020 20:58:16
User entered 'hypertension'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:37
User entered 'UN UNK 1995'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:37
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:37
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
Signature has been broken.	Brenda Grande (b) (4)	31 Mar 2021 14:35:39
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:06:37
User entered empty.	Karen Mylerberg (b) (4)	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:37
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jan 1995'	System	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '1995'	System	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:13:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 20:58:16

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:12:39
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Pedal edema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 06:02:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 06:02:37
Data point term sent to Coder	System	18 Sep 2020 21:35:58
DataPoint Un-verified.	Nicolle Mendez (b) (4)	18 Sep 2020 21:35:22
Coding entries removed.	Nicolle Mendez (b) (4)	18 Sep 2020 21:35:22
User entered 'BILATERAL lower EXTREMITY PEDAL EDEMA' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	18 Sep 2020 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:06:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Pedal edema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:19:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:19:40
Data point term sent to Coder	System	06 Sep 2020 21:00:18
User entered 'bilateral extremity pedal edema'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:46
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:46
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:46
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:06:46
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jan 2015'	System	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '2015'	System	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:13:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 20:59:29

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:01
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Tinea infections, PT: Body tinea, LLT: Tinea corporis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 21:00:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 21:00:41
Data point term sent to Coder	System	06 Sep 2020 21:00:17
User entered 'tinea corporis'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:52

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		16 Sep 2020 21:07:01
User entered 'UN UNK 2018'	Karen Mylerberg (b) (4)	06 Sep 2020 20:59:52
	(b) (4)	

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:01
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:52

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:01
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:52

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:01
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:52

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:01
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 20:59:52

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jan 2018'	System	06 Sep 2020 20:59:52

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '2018'	System	06 Sep 2020 20:59:52

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 20:59:52

US3112043

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:13:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 20:59:52

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:27
User coded data point as SOC: Reproductive system and breast disorders, HLT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 21:01:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 21:01:42
Data point term sent to Coder	System	06 Sep 2020 21:01:18
User entered 'Benign prostatic hyperplasia'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:27
User entered 'UN UNK 2019'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:27
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:27
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:27
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:27
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jan 2019'	System	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '2019'	System	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:13:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 21:00:29

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:17
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) (b) (4)	06 Sep 2020 21:01:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 21:01:41
Data point term sent to Coder	System	06 Sep 2020 21:01:18
User entered 'Seasonal allergies'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:17
User entered 'UN UNK 1975'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:17
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:17
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:17
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jan 1975'	System	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '1975'	System	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:13:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 21:00:49

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:38:01
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Podagra - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 20:09:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 20:09:49
User closed query 'Per Medical History Source, subject had "Cataract Surgery- Bilateral" Jan 2020. Please re-confirm if Condition that led to "Cataracts" should be added as part of Medical History that is relevant/significant, please add to eCRF Page.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 00:55:01
User closed query 'Per Medical History Source; "BPH -Started 2019", is noted in Source. Please re-confirm if "BPH" should be added to EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 00:54:59
User closed query 'Per DM CLR: Please specify the location of GOUT (e.g. Left Big Toe, Bilateral Knees etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 03:26:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 00:46:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 00:46:26
Data point term sent to Coder	System	22 Oct 2020 16:49:27

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the location of GOUT (e.g. Left Big Toe, Bilateral Knees etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Natalie Moy (b) (4)	22 Oct 2020 16:48:42
DataPoint Un-verified.	Natalie Moy (b) (4)	22 Oct 2020 16:48:35
Coding entries removed.	Natalie Moy (b) (4)	22 Oct 2020 16:48:35
User entered 'GOUT (primarily right big toe)' reason for change: Data Entry Error	Natalie Moy (b) (4)	22 Oct 2020 16:48:35
User opened query 'Per DM CLR: Please specify the location of GOUT (e.g. Left Big Toe, Bilateral Knees etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	22 Oct 2020 10:56:52
' (Site from DM).		
Query 'Per Medical History Source, subject had "Cataract Surgery- Bilateral" Jan 2020. Please re-confirm if Condition that led to "Cataracts" should be added as part of Medical History that is relevant/significant, please add to eCRF Page.' answered with 'confirmed and added' (Site from CRA).	Karen Mylerberg (b) (4)	01 Oct 2020 14:42:28
Query 'Per Medical History Source; "BPH -Started 2019", is noted in Source. Please re-confirm if "BPH" should be added to EDC.' answered with 'added' (Site from CRA).	Karen Mylerberg (b) (4)	01 Oct 2020 14:42:17
User opened query 'Per Medical History Source, subject had "Cataract Surgery- Bilateral" Jan 2020. Please re-confirm if Condition that led to "Cataracts" should be added as part of Medical History that is relevant/significant, please add to eCRF Page.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:28:58
User opened query 'Per Medical History Source; "BPH -Started 2019", is noted in Source. Please re-confirm if "BPH" should be added to EDC.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:16:40

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:07:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 21:01:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	06 Sep 2020 21:01:42
Data point term sent to Coder	System	06 Sep 2020 21:01:19
User entered 'Gout'	Karen Mylerberg (b) (4)	06 Sep 2020 21:01:04
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:40
User entered 'UN UNK 1995'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:01:04

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:40
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:01:04

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:01:04

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:40
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:01:04

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:07:40
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:01:04

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jan 1995'	System	06 Sep 2020 21:01:04

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '1995'	System	06 Sep 2020 21:01:04

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 21:01:04

US3112043

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:13:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	06 Sep 2020 21:01:04

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:37:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Oct 2020 14:42:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 14:42:45
Data point term sent to Coder	System	01 Oct 2020 14:41:23
User entered 'bilateral cataracts'	Karen Mylerberg (b) (4)	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:38:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Mar 2021 18:18:38
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	19 Mar 2021 18:18:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Mar 2021 18:18:27
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Mar 2021 18:18:27
User entered 'un UNK unk' (non-conformant).	Matthew Musikanth (b) (4)	19 Mar 2021 18:18:27
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:26:17
DataPoint Un-verified.	Matthew Musikanth (b) (4)	18 Mar 2021 20:10:49
Signature has been broken.	Matthew Musikanth (b) (4)	18 Mar 2021 20:10:49
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	18 Mar 2021 20:10:49
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:37:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered 'UN Jan 2020'	Karen Mylerberg (b) (4)	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:26:17
DataPoint Un-verified.	Matthew Musikanth	18 Mar 2021 20:10:49
Signature has been broken.	Matthew Musikanth	18 Mar 2021 20:10:49
User entered '1' reason for change: Data Entry Error	Matthew Musikanth	18 Mar 2021 20:10:49
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:37:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered '0'	Karen Mylerberg (b) (4)	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:37:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:37:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered 'un Jan 2020'	Karen Mylerberg (b) (4)	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:37:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered '0'	Karen Mylerberg (b) (4)	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	18 Mar 2021 20:10:49
User entered 'Jan 2020'	System	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered empty.	System	18 Mar 2021 20:10:49
User entered '2020'	System	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jan 2020'	System	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:13:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '2020'	System	01 Oct 2020 14:40:42

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:36:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:59:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:59:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 14:42:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 14:42:44
Data point term sent to Coder	System	01 Oct 2020 14:41:24
User entered 'bilateral cataract surgery'	Karen Mylerberg (b) (4)	01 Oct 2020 14:41:10

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:36:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered 'UN Jan 2020'	Karen Mylerberg (b) (4)	01 Oct 2020 14:41:10

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:36:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered '0'	Karen Mylerberg (b) (4)	01 Oct 2020 14:41:10

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:36:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	System	01 Oct 2020 14:41:26
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	Karen Mylerberg (b) (4)	01 Oct 2020 14:41:26
User entered 'Yes (Y)'	(b) (4)	
	System	01 Oct 2020 14:41:10
	Karen Mylerberg (b) (4)	01 Oct 2020 14:41:10
	(b) (4)	

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:36:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered 'Un Jan 2020'	Karen Mylerberg (b) (4)	01 Oct 2020 14:41:10

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:36:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered '0'	Karen Mylerberg (b) (4)	01 Oct 2020 14:41:10

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jan 2020'	System	01 Oct 2020 14:41:10

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '2020'	System	01 Oct 2020 14:41:10

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'Jan 2020'	System	01 Oct 2020 14:41:10

US3112043

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:13:17

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '2020'	System	01 Oct 2020 14:41:10

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:09:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:09:15
User entered '31 Jul 2020'	(b) (4), (b) (6)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:35:10
User closed query 'Per Source; Time of Assessment = 08:55 AM. Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:35:08
Query 'Per Source; Time of Assessment = 08:55 AM. Karen Mylerberg Please re-confirm with Source and Correct.' answered with 'confirmed and corrected' (Site from CRA).	Karen Mylerberg (b) (4)	30 Sep 2020 15:15:11
User entered '08:55' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	30 Sep 2020 15:14:51
User opened query 'Per Source; Time of Assessment = 08:55 AM. Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 21:09:52
User entered '09:39'	(b) (4), (b) (6)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '31 Jul 2020 08:55'	System	30 Sep 2020 15:14:51
User entered '31 Jul 2020 09:39'	System	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:35:43
User closed query 'Per Source; Height = 67 inches (5 Ft 7 In). Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:35:41
Query 'Per Source; Height = 67 inches (5 Ft 7 In). Please re-confirm with Source and correct.' answered with 'confirmed and corrected' (Site from CRA).	Karen Mylerberg (b) (4)	30 Sep 2020 15:15:15
User entered '67' in reason for change: Data Entry Error	(b) (4)	30 Sep 2020 15:14:51
User opened query 'Per Source; Height = 67 inches (5 Ft 7 In). Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 21:14:47
User entered '72.0' in	(b) (4), (b) (6)	01 Aug 2020 01:44:27
DataPoint set to visible.	System	31 Jul 2020 18:11:32

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:36:02
User closed query 'Per Source; Weight = 254.6 lbs. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:36:00
Query 'Per Source; Weight = 254.6 lbs. Please re-confirm with Source and correct.' answered with 'confirmed and corrected' (Site from CRA).	Karen Mylerberg (b) (4)	30 Sep 2020 15:15:45
User entered '254.6' lb reason for change: Data Entry Error	Karen Mylerberg (b) (4)	30 Sep 2020 15:14:51
User opened query 'Per Source; Weight = 254.6 lbs. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 21:22:43
User entered '208.0' lb	(b) (4), (b) (6)	01 Aug 2020 01:44:27
DataPoint set to visible.	System	31 Jul 2020 18:11:32

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered '39.95937'	System	30 Sep 2020 15:14:51
Amendment Manager: User entered '28.26886'	System	16 Sep 2020 23:39:43
User entered '28.3'	System	01 Aug 2020 01:44:27
DataPoint set to visible.	System	31 Jul 2020 18:11:32

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'kg/m2'	System	01 Aug 2020 01:44:27
DataPoint set to visible.	System	31 Jul 2020 18:11:32

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:22:50
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)	07 Sep 2020 02:30:30
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 02:25:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Sep 2020 02:25:46
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)	28 Aug 2020 13:21:19
User entered '98.1' F	(b) (4), (b) (6)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4)	16 Sep 2020 21:22:51
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 02:25:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:22:53
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4)	16 Sep 2020 21:22:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Sep 2020 02:25:46
User entered '83'	Karen Mylerberg (b) (4)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'bpm'	System	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4)	16 Sep 2020 21:22:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Sep 2020 02:25:46
User entered '15'	Karen Mylerberg (b) (4)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'breaths/min'	System	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4)	16 Sep 2020 21:22:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Sep 2020 02:25:46
User entered '125'	Karen Mylerberg (b) (4)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'mmHg'	System	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4)	16 Sep 2020 21:23:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Sep 2020 02:25:46
User entered '73'	Karen Mylerberg (b) (4)	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User entered 'mmHg'	System	01 Aug 2020 01:44:27

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21

US3112043

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21

US3112043

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:29:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Aug 2020 01:14:09

US3112043

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:29:53
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 11:58:01
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		26 Aug 2020 20:02:11
User entered '31 Jul 2020'	(b) (4), (b) (6)	01 Aug 2020 01:14:09

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

[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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:31:42
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:31:45
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:31:47
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:31:52
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

[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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:31:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

[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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:05
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

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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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:06
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:08
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4)	30 Sep 2020 18:37:03
User closed query 'Per Source; Please update "Other = Yes; Realtor". ' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:37:01
Query 'Per Source; Please update "Other = Yes; Realtor". ' answered with 'updated' (Site from CRA).	Karen Mylerberg (b) (4)	30 Sep 2020 15:18:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	30 Sep 2020 15:18:39
User opened query 'Per Source; Please update "Other = Yes; Realtor". ' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 21:31:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:37:04
User closed query 'Occupational Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	30 Sep 2020 15:18:51
User entered 'realtor' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 15:18:51
User opened query 'Occupational Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	30 Sep 2020 15:18:39
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:15:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Aug 2020 01:15:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:17
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:18
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:20
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

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 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:22
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:24
User entered '0'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Aug 2020 01:15:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:13:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:32:21
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:38:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:29
User entered 'resident in a community with ongoing person to person transmission'	(b) (4), (b) (6)	01 Aug 2020 01:15:13

US3112043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:32:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Aug 2020 01:15:31

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:43
User entered '31 Jul 2020'	(b) (4), (b) (6)	01 Aug 2020 01:15:31

US3112043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Aug 2020 01:15:31

US3112043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'VISIT1'	System	01 Aug 2020 01:15:31

US3112043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:50
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:59:07

US3112043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:17

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:50
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:30:32
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:30:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 16:59:07
User entered '184250' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:59:07

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:17

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:50
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:59:07

US3112043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:17

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:50
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:18:05

US3112043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:17

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:50
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:18:05

US3112043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:17

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:50
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:18:05

US3112043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:50
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:18:05

US3112043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:13:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:32:50
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:18:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:33:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:53:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:33:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:53:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
User entered '31 Jul 2020'	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
Query 'Per CDM: Please confirm if time of assessment is correct. Screening vitals were assessed at 09:39. ' canceled (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:32:44
User opened query 'Per CDM: Please confirm if time of assessment is correct. Screening vitals were assessed at 09:39. ' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 18:32:33
User entered '08:55'	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered '31 Jul 2020 08:55'	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
User entered '97.9' F	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Aug 2020 23:35:59
User entered 'Oral (Oral)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	02 Aug 2020 23:35:59
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 17:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Aug 2020 17:37:06
User entered '50' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Aug 2020 17:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'bpm'	System	03 Aug 2020 17:37:06
User entered empty.	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 17:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Aug 2020 17:37:06
User entered '16' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Aug 2020 17:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'breaths/min'	System	03 Aug 2020 17:37:06
User entered empty.	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 17:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Aug 2020 17:37:06
User entered '133' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Aug 2020 17:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'mmHg'	System	03 Aug 2020 17:37:06
User entered empty.	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:27
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 17:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Aug 2020 17:37:06
User entered '070' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Aug 2020 17:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'mmHg'	System	03 Aug 2020 17:37:06
User entered empty.	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:33:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:13:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:53:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User entered '31 Jul 2020'	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 20:00:49
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Vitals obtained at least 30 minutes post dosing per protocol' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	02 Aug 2020 23:36:12
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		01 Aug 2020 01:19:42
User entered '11:19'	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered '31 Jul 2020 11:19'	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User entered '97.6' F	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Aug 2020 23:35:59
User entered 'Oral (Oral)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	02 Aug 2020 23:35:59
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 17:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Aug 2020 17:37:06
User entered '52' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Aug 2020 17:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'bpm'	System	03 Aug 2020 17:37:06
User entered empty.	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 17:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Aug 2020 17:37:06
User entered '14' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Aug 2020 17:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'breaths/min'	System	03 Aug 2020 17:37:06
User entered empty.	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 17:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Aug 2020 17:37:06
User entered '124' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Aug 2020 17:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'mmHg'	System	03 Aug 2020 17:37:06
User entered empty.	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:55:32
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Aug 2020 17:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Aug 2020 17:37:06
User entered '086' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Aug 2020 17:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 01:19:42
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:19:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'mmHg'	System	03 Aug 2020 17:37:06
User entered empty.	System	01 Aug 2020 01:19:42

US3112043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:56:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Aug 2020 01:20:18

US3112043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:56:04
User entered '31 Jul 2020'	(b) (4), (b) (6)	01 Aug 2020 01:20:18

US3112043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:57:18
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:57:18
User entered empty.	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:57:18
User entered empty.	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:57:18
User entered '31 Jul 2020'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:57:18
User entered '10:48'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered '31 Jul 2020 10:48'	System	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:57:18
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 21:57:18
User entered 'ONCE'	System	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 18:11:51

US3112043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:57:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Aug 2020 01:20:56

US3112043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:57:46
User entered '31 Jul 2020'	(b) (4), (b) (6)	01 Aug 2020 01:20:56

US3112043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:57:46
User entered '09:26'	(b) (4), (b) (6)	01 Aug 2020 01:20:56

US3112043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered '31 Jul 2020 09:26'	System	01 Aug 2020 01:20:56

US3112043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:35
User entered '31 Jul 2020'	(b) (4), (b) (6)	01 Aug 2020 01:21:35

US3112043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Aug 2020 01:21:35

US3112043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Aug 2020 01:21:35

US3112043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:17

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:35
User entered '09:26'	(b) (4), (b) (6)	01 Aug 2020 01:21:35

US3112043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered '31 Jul 2020 09:26'	System	01 Aug 2020 01:21:35

US3112043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Aug 2020 01:21:35

US3112043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:35
User entered 'No (N)'	(b) (4), (b) (6)	01 Aug 2020 01:21:35

US3112043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:35
User entered empty.	(b) (4), (b) (6)	01 Aug 2020 01:21:35

US3112043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered empty.	System	01 Aug 2020 01:21:35

US3112043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:59:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Aug 2020 01:21:40

US3112043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'I'	System	01 Aug 2020 01:21:40

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:21:47', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '34e9e0e1-7f8e-4af0-962c-7dce54d77ce4' User entered 'Yes (Y)'	System	31 Jul 2020 18:23:51
	System	31 Jul 2020 18:23:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:21:50', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '34e9e0e1-7f8e-4af0-962c-7dce54d77ce4' User entered '97.4'	System	31 Jul 2020 18:23:51
	System	31 Jul 2020 18:23:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:21:59', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '34e9e0e1-7f8e-4af0-962c-7dce54d77ce4' User entered 'No (N)'	System	31 Jul 2020 18:23:51
	System	31 Jul 2020 18:23:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:23:48', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '34e9e0e1-7f8e-4af0-962c-7dce54d77ce4' User entered '31 Jul 2020 11:23'	System	31 Jul 2020 18:23:51
	System	31 Jul 2020 18:23:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '31 Jul 2020 11:08'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '31 Jul 2020 13:38'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:30:58', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '29b91e75-b8cc-425e-89b4-aa4361f0b3d1' User entered 'Yes (Y)'	System	01 Aug 2020 01:31:29
	System	01 Aug 2020 01:31:29

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:31:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '29b91e75-b8cc-425e-89b4-aa4361f0b3d1' User entered '97.4'	System	01 Aug 2020 01:31:29
	System	01 Aug 2020 01:31:29

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:31:15', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '29b91e75-b8cc-425e-89b4-aa4361f0b3d1' User entered 'No (N)'	System	01 Aug 2020 01:31:29
	System	01 Aug 2020 01:31:29

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:31:27', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '29b91e75-b8cc-425e-89b4-aa4361f0b3d1' User entered '31 Jul 2020 18:31'	System	01 Aug 2020 01:31:29
	System	01 Aug 2020 01:31:29

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '31 Jul 2020 14:33'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 2'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:37:53', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '9531f8a0-740e-4d7c-8458-e4e9bb402745' User entered 'Yes (Y)'	System	01 Aug 2020 19:38:27
	System	01 Aug 2020 19:38:27

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:38:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '9531f8a0-740e-4d7c-8458-e4e9bb402745' User entered '97.4'	System	01 Aug 2020 19:38:27
	System	01 Aug 2020 19:38:27

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:38:18', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '9531f8a0-740e-4d7c-8458-e4e9bb402745'	System	01 Aug 2020 19:38:27
User entered 'No (N)'	System	01 Aug 2020 19:38:27

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:38:26', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '9531f8a0-740e-4d7c-8458-e4e9bb402745' User entered '01 Aug 2020 12:38'	System	01 Aug 2020 19:38:27
	System	01 Aug 2020 19:38:27

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 3'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:10:35', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '60c6b8b5-3b59-435f-93d5-82c005eef800' User entered 'Yes (Y)'	System	03 Aug 2020 07:10:57
	System	03 Aug 2020 07:10:57

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:10:43', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '60c6b8b5-3b59-435f-93d5-82c005eef800' User entered '97.4'	System	03 Aug 2020 07:10:57
	System	03 Aug 2020 07:10:57

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:10:48', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '60c6b8b5-3b59-435f-93d5-82c005eef800'	System	03 Aug 2020 07:10:57
User entered 'No (N)'	System	03 Aug 2020 07:10:57

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:10:55', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '60c6b8b5-3b59-435f-93d5-82c005eef800' User entered '03 Aug 2020 00:10'	System	03 Aug 2020 07:10:57
	System	03 Aug 2020 07:10:57

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 4'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:19:56', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0cc77bc3-285d-4774-a0b7-e2d87c133427' User entered 'Yes (Y)'	System	04 Aug 2020 07:20:22
	System	04 Aug 2020 07:20:22

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:20:05', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0cc77bc3-285d-4774-a0b7-e2d87c133427' User entered '97.4'	System	04 Aug 2020 07:20:22
	System	04 Aug 2020 07:20:22

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:20:10', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0cc77bc3-285d-4774-a0b7-e2d87c133427' User entered 'No (N)'	System	04 Aug 2020 07:20:22
	System	04 Aug 2020 07:20:22

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:20:18', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0cc77bc3-285d-4774-a0b7-e2d87c133427' User entered '04 Aug 2020 00:20'	System	04 Aug 2020 07:20:22
	System	04 Aug 2020 07:20:22

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 5'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:13', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '964d6bea-53dc-42fd-8b66-495ef752ae2a' User entered 'Yes (Y)'	System	04 Aug 2020 22:33:34
	System	04 Aug 2020 22:33:34

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:24', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '964d6bea-53dc-42fd-8b66-495ef752ae2a' User entered '96.8'	System	04 Aug 2020 22:33:34
	System	04 Aug 2020 22:33:34

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:29', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '964d6bea-53dc-42fd-8b66-495ef752ae2a' User entered 'No (N)'	System	04 Aug 2020 22:33:34
	System	04 Aug 2020 22:33:34

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:32', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '964d6bea-53dc-42fd-8b66-495ef752ae2a' User entered '04 Aug 2020 15:33'	System	04 Aug 2020 22:33:34
	System	04 Aug 2020 22:33:34

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 6'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:38:33', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '202255e2-4fb6-4da0-a127-d02fc57a1af4' User entered 'Yes (Y)'	System	06 Aug 2020 07:39:01
	System	06 Aug 2020 07:39:01

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:38:43', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '202255e2-4fb6-4da0-a127-d02fc57a1af4' User entered '97.5'	System	06 Aug 2020 07:39:01
	System	06 Aug 2020 07:39:01

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:38:49', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '202255e2-4fb6-4da0-a127-d02fc57a1af4'	System	06 Aug 2020 07:39:01
User entered 'No (N)'	System	06 Aug 2020 07:39:01

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '202255e2-4fb6-4da0-a127-d02fc57a1af4' User entered '06 Aug 2020 00:39'	System	06 Aug 2020 07:39:01
	System	06 Aug 2020 07:39:01

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 7'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:53:25', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5a2739c1-2cb1-4f00-a9b7-67539f422c1f' User entered 'Yes (Y)'	System	07 Aug 2020 01:54:10
	System	07 Aug 2020 01:54:10

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:53:36', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5a2739c1-2cb1-4f00-a9b7-67539f422c1f' User entered '97.5'	System	07 Aug 2020 01:54:10
	System	07 Aug 2020 01:54:10

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:53:59', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5a2739c1-2cb1-4f00-a9b7-67539f422c1f' User entered 'No (N)'	System	07 Aug 2020 01:54:10
	System	07 Aug 2020 01:54:10

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:54:07', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5a2739c1-2cb1-4f00-a9b7-67539f422c1f' User entered '06 Aug 2020 18:54'	System	07 Aug 2020 01:54:10
	System	07 Aug 2020 01:54:10

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:24:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5304b8d3-4acf-49a5-b24e-0f21eb6160ac' User entered 'None (1)'	System	31 Jul 2020 18:24:46
	System	31 Jul 2020 18:24:46

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:24:15', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5304b8d3-4acf-49a5-b24e-0f21eb6160ac' User entered 'No (N)'	System	31 Jul 2020 18:24:46
	System	31 Jul 2020 18:24:46

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:24:25', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5304b8d3-4acf-49a5-b24e-0f21eb6160ac' User entered 'No (N)'	System	31 Jul 2020 18:24:46
	System	31 Jul 2020 18:24:46

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:24:39', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5304b8d3-4acf-49a5-b24e-0f21eb6160ac' User entered 'None (1)'	System	31 Jul 2020 18:24:46
	System	31 Jul 2020 18:24:46

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:24:44', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5304b8d3-4acf-49a5-b24e-0f21eb6160ac' User entered '31 Jul 2020 11:24'	System	31 Jul 2020 18:24:46
	System	31 Jul 2020 18:24:46

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '31 Jul 2020 11:08'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '31 Jul 2020 13:38'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:32:18', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '58066dbe-9275-4769-8fba-03a3ae9f32e5' User entered 'None (1)'	System	01 Aug 2020 01:32:50
	System	01 Aug 2020 01:32:50

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:32:26', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '58066dbe-9275-4769-8fba-03a3ae9f32e5' User entered 'No (N)'	System	01 Aug 2020 01:32:50
	System	01 Aug 2020 01:32:50

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:32:32', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '58066dbe-9275-4769-8fba-03a3ae9f32e5' User entered 'No (N)'	System	01 Aug 2020 01:32:50
	System	01 Aug 2020 01:32:50

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:32:40', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '58066dbe-9275-4769-8fba-03a3ae9f32e5' User entered 'None (1)'	System	01 Aug 2020 01:32:50
	System	01 Aug 2020 01:32:50

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:32:45', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '58066dbe-9275-4769-8fba-03a3ae9f32e5' User entered '31 Jul 2020 18:32'	System	01 Aug 2020 01:32:50
	System	01 Aug 2020 01:32:50

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '31 Jul 2020 14:33'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 2'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:38:57', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '4a11905c-1251-429f-b8c9-5eca92059093'	System	01 Aug 2020 19:39:49
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 19:39:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:39:02', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '4a11905c-1251-429f-b8c9-5eca92059093' User entered 'No (N)'	System	01 Aug 2020 19:39:49
	System	01 Aug 2020 19:39:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:39:15', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '4a11905c-1251-429f-b8c9-5eca92059093' User entered 'No (N)'	System	01 Aug 2020 19:39:49
	System	01 Aug 2020 19:39:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:39:40', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '4a11905c-1251-429f-b8c9-5eca92059093'	System	01 Aug 2020 19:39:49
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 19:39:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:39:47', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '4a11905c-1251-429f-b8c9-5eca92059093' User entered '01 Aug 2020 12:39'	System	01 Aug 2020 19:39:49
	System	01 Aug 2020 19:39:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 3'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:11:23', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'a7b3553a-3188-483c-aa72-475aa424cbc7'	System	03 Aug 2020 07:11:49
User entered 'None (1)'	System	03 Aug 2020 07:11:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:11:28', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'a7b3553a-3188-483c-aa72-475aa424cbc7' User entered 'No (N)'	System	03 Aug 2020 07:11:49
	System	03 Aug 2020 07:11:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:11:35', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'a7b3553a-3188-483c-aa72-475aa424cbc7' User entered 'No (N)'	System	03 Aug 2020 07:11:49
	System	03 Aug 2020 07:11:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:11:41', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'a7b3553a-3188-483c-aa72-475aa424cbc7' User entered 'None (1)'	System	03 Aug 2020 07:11:49
	System	03 Aug 2020 07:11:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:11:47', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'a7b3553a-3188-483c-aa72-475aa424cbc7' User entered '03 Aug 2020 00:11'	System	03 Aug 2020 07:11:49
	System	03 Aug 2020 07:11:49

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 4'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:20:28', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0583a97-9a04-46b1-9b61-7f18de923428'	System	04 Aug 2020 07:20:53
User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 07:20:53

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:20:33', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0583a97-9a04-46b1-9b61-7f18de923428' User entered 'No (N)'	System	04 Aug 2020 07:20:53
	System	04 Aug 2020 07:20:53

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:20:37', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0583a97-9a04-46b1-9b61-7f18de923428' User entered 'No (N)'	System	04 Aug 2020 07:20:53
	System	04 Aug 2020 07:20:53

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:20:46', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0583a97-9a04-46b1-9b61-7f18de923428' User entered 'None (1)'	System	04 Aug 2020 07:20:53
	System	04 Aug 2020 07:20:53

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:20:50', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0583a97-9a04-46b1-9b61-7f18de923428' User entered '04 Aug 2020 00:20'	System	04 Aug 2020 07:20:53
	System	04 Aug 2020 07:20:53

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 5'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:38', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f2aed8c9-3462-4e0b-b19a-0b63b2400c2c' User entered 'None (1)'	System	04 Aug 2020 22:33:54
	System	04 Aug 2020 22:33:54

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:42', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f2aed8c9-3462-4e0b-b19a-0b63b2400c2c' User entered 'No (N)'	System	04 Aug 2020 22:33:54
	System	04 Aug 2020 22:33:54

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:45', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f2aed8c9-3462-4e0b-b19a-0b63b2400c2c' User entered 'No (N)'	System	04 Aug 2020 22:33:54
	System	04 Aug 2020 22:33:54

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:48', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f2aed8c9-3462-4e0b-b19a-0b63b2400c2c' User entered 'None (1)'	System	04 Aug 2020 22:33:54
	System	04 Aug 2020 22:33:54

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:50', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f2aed8c9-3462-4e0b-b19a-0b63b2400c2c' User entered '04 Aug 2020 15:33'	System	04 Aug 2020 22:33:54
	System	04 Aug 2020 22:33:54

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 6'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:24', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93ab0ca0-7dba-419e-82bb-d9cc7699e663'	System	06 Aug 2020 07:39:38
User entered 'None (1)'	System	06 Aug 2020 07:39:38

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:21', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93ab0ca0-7dba-419e-82bb-d9cc7699e663' User entered 'No (N)'	System	06 Aug 2020 07:39:38
	System	06 Aug 2020 07:39:38

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:18', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93ab0ca0-7dba-419e-82bb-d9cc7699e663' User entered 'No (N)'	System	06 Aug 2020 07:39:38
	System	06 Aug 2020 07:39:38

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:29', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93ab0ca0-7dba-419e-82bb-d9cc7699e663' User entered 'None (1)'	System	06 Aug 2020 07:39:38
	System	06 Aug 2020 07:39:38

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:37', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93ab0ca0-7dba-419e-82bb-d9cc7699e663' User entered '06 Aug 2020 00:39'	System	06 Aug 2020 07:39:38
	System	06 Aug 2020 07:39:38

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 7'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:54:14', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '1ba0f631-6bbb-470f-be3b-b154960502db' User entered 'None (1)'	System	07 Aug 2020 01:54:36
	System	07 Aug 2020 01:54:36

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:54:17', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '1ba0f631-6bbb-470f-be3b-b154960502db' User entered 'No (N)'	System	07 Aug 2020 01:54:36
	System	07 Aug 2020 01:54:36

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:54:21', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '1ba0f631-6bbb-470f-be3b-b154960502db' User entered 'No (N)'	System	07 Aug 2020 01:54:36
	System	07 Aug 2020 01:54:36

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:54:31', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '1ba0f631-6bbb-470f-be3b-b154960502db' User entered 'None (1)'	System	07 Aug 2020 01:54:36
	System	07 Aug 2020 01:54:36

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:54:33', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '1ba0f631-6bbb-470f-be3b-b154960502db' User entered '06 Aug 2020 18:54'	System	07 Aug 2020 01:54:36
	System	07 Aug 2020 01:54:36

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:24:51', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '404f38ae-8833-4a04-b475-b353346387e0' User entered 'None (0)'	System	31 Jul 2020 18:25:14
	System	31 Jul 2020 18:25:14

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:24:54', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '404f38ae-8833-4a04-b475-b353346387e0' User entered 'None (0)'	System	31 Jul 2020 18:25:14
	System	31 Jul 2020 18:25:14

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:24:56', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '404f38ae-8833-4a04-b475-b353346387e0' User entered 'None (0)'	System	31 Jul 2020 18:25:14
	System	31 Jul 2020 18:25:14

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:24:59', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '404f38ae-8833-4a04-b475-b353346387e0' User entered 'None (0)'	System	31 Jul 2020 18:25:14
	System	31 Jul 2020 18:25:14

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:25:01', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '404f38ae-8833-4a04-b475-b353346387e0' User entered 'None (0)'	System	31 Jul 2020 18:25:14
	System	31 Jul 2020 18:25:14

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:25:03', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '404f38ae-8833-4a04-b475-b353346387e0' User entered 'None (0)'	System	31 Jul 2020 18:25:14
	System	31 Jul 2020 18:25:14

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:25:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '404f38ae-8833-4a04-b475-b353346387e0' User entered 'No (N)'	System	31 Jul 2020 18:25:14
	System	31 Jul 2020 18:25:14

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T11:25:12', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '404f38ae-8833-4a04-b475-b353346387e0' User entered '31 Jul 2020 11:25'	System	31 Jul 2020 18:25:14
	System	31 Jul 2020 18:25:14

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '31 Jul 2020 11:08'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '31 Jul 2020 13:38'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:32:53', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5c3701fe-bff7-4508-8be8-82dbd15b2798' User entered 'None (0)'	System	01 Aug 2020 01:34:11
	System	01 Aug 2020 01:34:11

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:32:57', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5c3701fe-bff7-4508-8be8-82dbd15b2798' User entered 'None (0)'	System	01 Aug 2020 01:34:11
	System	01 Aug 2020 01:34:11

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:33:44', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5c3701fe-bff7-4508-8be8-82dbd15b2798'	System	01 Aug 2020 01:34:11
User entered 'No interference with activity (1)'	System	01 Aug 2020 01:34:11

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:33:48', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5c3701fe-bff7-4508-8be8-82dbd15b2798' User entered 'None (0)'	System	01 Aug 2020 01:34:11
	System	01 Aug 2020 01:34:11

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:33:55', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5c3701fe-bff7-4508-8be8-82dbd15b2798' User entered 'None (0)'	System	01 Aug 2020 01:34:11
	System	01 Aug 2020 01:34:11

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:33:58', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5c3701fe-bff7-4508-8be8-82dbd15b2798' User entered 'None (0)'	System	01 Aug 2020 01:34:11
	System	01 Aug 2020 01:34:11

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:34:06', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5c3701fe-bff7-4508-8be8-82dbd15b2798' User entered 'No (N)'	System	01 Aug 2020 01:34:11
	System	01 Aug 2020 01:34:11

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-07-31T18:34:10', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5c3701fe-bff7-4508-8be8-82dbd15b2798' User entered '31 Jul 2020 18:34'	System	01 Aug 2020 01:34:11
	System	01 Aug 2020 01:34:11

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '31 Jul 2020 14:33'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 2'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:39:55', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6786bab6-360f-4f89-94c2-89cc7d791d37' User entered 'None (0)'	System	01 Aug 2020 19:40:41
	System	01 Aug 2020 19:40:41

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:40:02', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6786bab6-360f-4f89-94c2-89cc7d791d37'	System	01 Aug 2020 19:40:41
User entered 'No interference with activity (1)'	System	01 Aug 2020 19:40:41

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:40:11', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6786bab6-360f-4f89-94c2-89cc7d791d37'	System	01 Aug 2020 19:40:41
User entered 'No interference with activity (1)'	System	01 Aug 2020 19:40:41

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:40:19', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6786bab6-360f-4f89-94c2-89cc7d791d37' User entered 'None (0)'	System	01 Aug 2020 19:40:41
	System	01 Aug 2020 19:40:41

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:40:23', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6786bab6-360f-4f89-94c2-89cc7d791d37' User entered 'None (0)'	System	01 Aug 2020 19:40:41
	System	01 Aug 2020 19:40:41

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:40:25', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6786bab6-360f-4f89-94c2-89cc7d791d37' User entered 'None (0)'	System	01 Aug 2020 19:40:41
	System	01 Aug 2020 19:40:41

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:40:31', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6786bab6-360f-4f89-94c2-89cc7d791d37'	System	01 Aug 2020 19:40:41
User entered 'No (N)'	System	01 Aug 2020 19:40:41

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-01T12:40:37', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6786bab6-360f-4f89-94c2-89cc7d791d37' User entered '01 Aug 2020 12:40'	System	01 Aug 2020 19:40:41
	System	01 Aug 2020 19:40:41

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 3'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:11:57', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '28c64824-a3ca-4af1-95fc-abe54a8890ea' User entered 'None (0)'	System	03 Aug 2020 07:12:30
	System	03 Aug 2020 07:12:30

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:12:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '28c64824-a3ca-4af1-95fc-abe54a8890ea' User entered 'None (0)'	System	03 Aug 2020 07:12:30
	System	03 Aug 2020 07:12:30

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:12:12', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '28c64824-a3ca-4af1-95fc-abe54a8890ea' User entered 'None (0)'	System	03 Aug 2020 07:12:30
	System	03 Aug 2020 07:12:30

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:12:15', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '28c64824-a3ca-4af1-95fc-abe54a8890ea' User entered 'None (0)'	System	03 Aug 2020 07:12:30
	System	03 Aug 2020 07:12:30

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:12:18', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '28c64824-a3ca-4af1-95fc-abe54a8890ea' User entered 'None (0)'	System	03 Aug 2020 07:12:30
	System	03 Aug 2020 07:12:30

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:12:21', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '28c64824-a3ca-4af1-95fc-abe54a8890ea' User entered 'None (0)'	System	03 Aug 2020 07:12:30
	System	03 Aug 2020 07:12:30

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:12:25', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '28c64824-a3ca-4af1-95fc-abe54a8890ea' User entered 'No (N)'	System	03 Aug 2020 07:12:30
	System	03 Aug 2020 07:12:30

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-03T00:12:28', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '28c64824-a3ca-4af1-95fc-abe54a8890ea' User entered '03 Aug 2020 00:12'	System	03 Aug 2020 07:12:30
	System	03 Aug 2020 07:12:30

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 4'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:20:56', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93118d6c-e633-41de-bf1b-d06c7df33e18' User entered 'None (0)'	System	04 Aug 2020 07:22:51
	System	04 Aug 2020 07:22:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:21:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93118d6c-e633-41de-bf1b-d06c7df33e18' User entered 'None (0)'	System	04 Aug 2020 07:22:51
	System	04 Aug 2020 07:22:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:21:04', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93118d6c-e633-41de-bf1b-d06c7df33e18' User entered 'No interference with activity (1)'	System	04 Aug 2020 07:22:51
	System	04 Aug 2020 07:22:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:21:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93118d6c-e633-41de-bf1b-d06c7df33e18' User entered 'None (0)'	System	04 Aug 2020 07:22:51
	System	04 Aug 2020 07:22:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:21:12', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93118d6c-e633-41de-bf1b-d06c7df33e18' User entered 'None (0)'	System	04 Aug 2020 07:22:51
	System	04 Aug 2020 07:22:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:22:30', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93118d6c-e633-41de-bf1b-d06c7df33e18' User entered 'None (0)'	System	04 Aug 2020 07:22:51
	System	04 Aug 2020 07:22:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:22:44', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93118d6c-e633-41de-bf1b-d06c7df33e18' User entered 'No (N)'	System	04 Aug 2020 07:22:51
	System	04 Aug 2020 07:22:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T00:22:48', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '93118d6c-e633-41de-bf1b-d06c7df33e18' User entered '04 Aug 2020 00:22'	System	04 Aug 2020 07:22:51
	System	04 Aug 2020 07:22:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 5'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:56', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '26821b6b-c891-4984-8eda-b4c7dc6d4876' User entered 'None (0)'	System	04 Aug 2020 22:34:15
	System	04 Aug 2020 22:34:15

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:33:58', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '26821b6b-c891-4984-8eda-b4c7dc6d4876' User entered 'None (0)'	System	04 Aug 2020 22:34:15
	System	04 Aug 2020 22:34:15

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:34:01', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '26821b6b-c891-4984-8eda-b4c7dc6d4876' User entered 'None (0)'	System	04 Aug 2020 22:34:15
	System	04 Aug 2020 22:34:15

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:34:03', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '26821b6b-c891-4984-8eda-b4c7dc6d4876' User entered 'None (0)'	System	04 Aug 2020 22:34:15
	System	04 Aug 2020 22:34:15

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:34:05', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '26821b6b-c891-4984-8eda-b4c7dc6d4876' User entered 'None (0)'	System	04 Aug 2020 22:34:15
	System	04 Aug 2020 22:34:15

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:34:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '26821b6b-c891-4984-8eda-b4c7dc6d4876' User entered 'None (0)'	System	04 Aug 2020 22:34:15
	System	04 Aug 2020 22:34:15

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:34:11', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '26821b6b-c891-4984-8eda-b4c7dc6d4876' User entered 'No (N)'	System	04 Aug 2020 22:34:15
	System	04 Aug 2020 22:34:15

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-04T15:34:13', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '26821b6b-c891-4984-8eda-b4c7dc6d4876' User entered '04 Aug 2020 15:34'	System	04 Aug 2020 22:34:15
	System	04 Aug 2020 22:34:15

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 6'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:44', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66b5613c-dc89-4a53-8fb5-6d6889efa127' User entered 'None (0)'	System	06 Aug 2020 07:40:09
	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:47', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66b5613c-dc89-4a53-8fb5-6d6889efa127' User entered 'None (0)'	System	06 Aug 2020 07:40:09
	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:50', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66b5613c-dc89-4a53-8fb5-6d6889efa127' User entered 'None (0)'	System	06 Aug 2020 07:40:09
	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:55', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66b5613c-dc89-4a53-8fb5-6d6889efa127'	System	06 Aug 2020 07:40:09
User entered 'No interference with activity (1)'	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:39:57', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66b5613c-dc89-4a53-8fb5-6d6889efa127' User entered 'None (0)'	System	06 Aug 2020 07:40:09
	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:40:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66b5613c-dc89-4a53-8fb5-6d6889efa127' User entered 'None (0)'	System	06 Aug 2020 07:40:09
	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:40:05', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66b5613c-dc89-4a53-8fb5-6d6889efa127' User entered 'No (N)'	System	06 Aug 2020 07:40:09
	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T00:40:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66b5613c-dc89-4a53-8fb5-6d6889efa127' User entered '06 Aug 2020 00:40'	System	06 Aug 2020 07:40:09
	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 7'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:54:40', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'ded9f26f-5340-4412-b305-79300921a60d' User entered 'None (0)'	System	07 Aug 2020 01:55:18
	System	07 Aug 2020 01:55:18

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:54:55', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'ded9f26f-5340-4412-b305-79300921a60d' User entered 'None (0)'	System	07 Aug 2020 01:55:18
	System	07 Aug 2020 01:55:18

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:55:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'ded9f26f-5340-4412-b305-79300921a60d' User entered 'None (0)'	System	07 Aug 2020 01:55:18
	System	07 Aug 2020 01:55:18

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:55:04', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'ded9f26f-5340-4412-b305-79300921a60d' User entered 'None (0)'	System	07 Aug 2020 01:55:18
	System	07 Aug 2020 01:55:18

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:55:06', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'ded9f26f-5340-4412-b305-79300921a60d' User entered 'None (0)'	System	07 Aug 2020 01:55:18
	System	07 Aug 2020 01:55:18

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:55:09', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'ded9f26f-5340-4412-b305-79300921a60d' User entered 'None (0)'	System	07 Aug 2020 01:55:18
	System	07 Aug 2020 01:55:18

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:55:14', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'ded9f26f-5340-4412-b305-79300921a60d' User entered 'No (N)'	System	07 Aug 2020 01:55:18
	System	07 Aug 2020 01:55:18

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-06T18:55:16', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'ded9f26f-5340-4412-b305-79300921a60d' User entered '06 Aug 2020 18:55'	System	07 Aug 2020 01:55:18
	System	07 Aug 2020 01:55:18

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
Data entry locked.	System	06 Aug 2020 07:40:09
User entered 'Day 8'	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53

US3112043

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53

US3112043

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 07:40:09

US3112043

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:16:53
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 07:40:09

US3112043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:03:37
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 16:50:28

US3112043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:37
User entered '07 Aug 2020'	Matthew Musikanth (b) (4)	07 Aug 2020 16:50:28

US3112043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:37
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	07 Aug 2020 16:50:28

US3112043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:37
User entered empty.	Matthew Musikanth (b) (4)	07 Aug 2020 16:50:28

US3112043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:03:45
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Aug 2020 16:50:32

US3112043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'I'	System	07 Aug 2020 16:50:32

US3112043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	14 Aug 2020 19:56:08

US3112043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:33
User entered '14 Aug 2020'	Matthew Musikanth (b) (4)	14 Aug 2020 19:56:08

US3112043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:33
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	14 Aug 2020 19:56:08

US3112043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:33
User entered empty.	Matthew Musikanth (b) (4)	14 Aug 2020 19:56:08

US3112043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:04:57
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	14 Aug 2020 19:56:12

US3112043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:25:25
User entered 'I'	System	14 Aug 2020 19:56:12

US3112043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:36:55
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
User closed query 'Per Source; Please ensure Source Documents are Updated, since Subject Contact Made and Identity Verified is missing documentation in Source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:26:09
Query 'Per Source; Please ensure Source Documents are Updated, since Subject Contact Made and Identity Verified is missing documentation in Source.' answered with 'source for day 22 is completed and is filed in chart' (Site from CRA).	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 15:17:06
User opened query 'Per Source; Please ensure Source Documents are Updated, since Subject Contact Made and Identity Verified is missing documentation in Source.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:06:01
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Aug 2020 21:27:33

US3112043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:08
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4)	16 Sep 2020 22:16:23
User entered '21 Aug 2020'	Matthew Musikanth	21 Aug 2020 21:27:33
	(b) (4)	

US3112043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:08
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:36:58
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	21 Aug 2020 21:27:33

US3112043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:08
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4)	16 Sep 2020 22:16:26
User entered empty.	Matthew Musikanth	21 Aug 2020 21:27:33
	(b) (4)	

US3112043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:08
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4)	16 Sep 2020 22:16:09
User entered 'Yes (Y)'	Matthew Musikanth	21 Aug 2020 21:26:52
	(b) (4)	

US3112043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:27:08
User entered 'I'	System	21 Aug 2020 21:26:52

US3112043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:17:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 20:02:11

US3112043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:17:44
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 12:37:44
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Aug 2020 20:02:11
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 20:02:11

US3112043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:17:44
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Aug 2020 20:02:11

US3112043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'VISIT2'	System	26 Aug 2020 20:02:11

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:18:33
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '26 Aug 2020'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:18:39
User entered '11:17'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered '26 Aug 2020 11:17'	System	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:18:44
User entered '98.2' F	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:18:46
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:18:49
User entered empty.	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:05:44
User closed query 'Per Source; Pulse = 57 beats/min. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:05:41
Query 'Per Source; Pulse = 57 beats/min. Please re-confirm with Source and correct.' answered with 'data changed to reflect source' (Site from CRA).	Nicolle Mendez (b) (4)	29 Sep 2020 20:21:06
User entered '57' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	29 Sep 2020 20:20:20
User opened query 'Per Source; Pulse = 57 beats/min. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:19:35
User entered '54'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'bpm'	System	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:06:13
User closed query 'Per Source; Respiratory Rate = 15. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:06:10
Query 'Per Source; Respiratory Rate = 15. Please re-confirm with Source and correct.' answered with 'data changed to reflect source' (Site from CRA).	Nicolle Mendez (b) (4)	29 Sep 2020 20:21:09
User entered '15' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	29 Sep 2020 20:20:20
User opened query 'Per Source; Respiratory Rate = 15. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:20:10
User entered '16'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'breaths/min'	System	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:06:19
User closed query 'Per Source: Systolic BP = 110. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:06:17
Query 'Per Source: Systolic BP = 110. Please re-confirm with Source and correct.' answered with 'data changed to reflect source' (Site from CRA).	Nicolle Mendez (b) (4)	29 Sep 2020 20:21:12
User entered '110' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	29 Sep 2020 20:20:20
User opened query 'Per Source: Systolic BP = 110. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:20:47
User entered '102'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'mmHg'	System	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:06:27
User closed query 'Per Source; Diastolic = 56. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:06:25
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 10:42:12
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Nicolle Mendez (b) (4)	29 Sep 2020 20:21:32
Query 'Per Source; Diastolic = 56. Please re-confirm with Source and correct.' answered with 'data changed to reflect source' (Site from CRA).	Nicolle Mendez (b) (4)	29 Sep 2020 20:21:18
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	29 Sep 2020 20:20:20
User entered '056' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	29 Sep 2020 20:20:20
User opened query 'Per Source; Diastolic = 56. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:21:16
User entered '062'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:13:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'mmHg'	System	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:21:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:21:48
User entered '26 Aug 2020'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:21:52
User entered '13:16'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered '26 Aug 2020 13:16'	System	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:21:54
User entered '98.2' F	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:21:56
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

US3112043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:21:58
User entered empty.	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:06:59
User closed query 'Per Source; Pulse = 54. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:06:57
Query 'Per Source; Pulse = 54. Please re-confirm with Source and correct.' answered with 'data updated to reflect source' (Site from CRA).	Nicolle Mendez (b) (4)	29 Sep 2020 20:25:08
User entered '54' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	29 Sep 2020 20:24:42
User opened query 'Per Source; Pulse = 54. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:22:35
User entered '57'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'bpm'	System	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:07:03
User closed query 'Per Source; RR = 16. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:07:01
Query 'Per Source; RR = 16. Please re-confirm with Source and correct.' answered with 'data updated to reflect source' (Site from CRA).	Nicolle Mendez (b) (4)	29 Sep 2020 20:25:06
User entered '16' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	29 Sep 2020 20:24:42
User opened query 'Per Source; RR = 16. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:23:04
User entered '15'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'breaths/min'	System	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:07:07
User closed query 'Per Source; Systolic = 102. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:07:06
Query 'Per Source; Systolic = 102. Please re-confirm with Source and correct.' answered with 'data updated to reflect source' (Site from CRA).	Nicolle Mendez (b) (4)	29 Sep 2020 20:25:04
User entered '102' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	29 Sep 2020 20:24:42
User opened query 'Per Source; Systolic = 102. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:23:37
User entered '110'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'mmHg'	System	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:03:22
User closed query 'Per Source; Diastolic = 54. Please re-confirm with Source and correct' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:03:19
Query 'Per Source; Diastolic = 54. Please re-confirm with Source and correct' answered with 'post dose was 62 for visit 2' (Site from CRA).	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 23:23:45
User opened query 'Per Source; Diastolic = 54. Please re-confirm with Source and correct' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:07:35
User closed query 'Per Source; Diastolic = 54. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:07:35
Query 'Per Source; Diastolic = 54. Please re-confirm with Source and correct.' answered with 'data updated to reflect source' (Site from CRA).	Nicolle Mendez (b) (4)	29 Sep 2020 20:25:00
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	29 Sep 2020 20:24:42
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	29 Sep 2020 20:24:42
User entered '62' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	29 Sep 2020 20:24:42
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:39:43
User opened query 'Per Source; Diastolic = 54. Please re-confirm with Source and correct.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:24:37
User entered '056'	Karen Mylerberg (b) (4) (b) (4)	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:13:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'mmHg'	System	06 Sep 2020 21:02:45

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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:08:14
User closed query 'Visit 2 Source Notes Dated 26AUG2020 - Indicates that "Yes" Lymph Nodes were reviewed; Investigator Signed this Source Note dated 26AUG2020. Please re-review source and correct page.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:08:13
Query 'Visit 2 Source Notes Dated 26AUG2020 - Indicates that "Yes" Lymph Nodes were reviewed; Investigator Signed this Source Note dated 26AUG2020. Please re-review source and correct page.' answered with 'completed' (Site from CRA).	Karen Mylerberg (b) (4)	01 Oct 2020 14:32:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	01 Oct 2020 14:32:28
User opened query 'Visit 2 Source Notes Dated 26AUG2020 - Indicates that "Yes" Lymph Nodes were reviewed; Investigator Signed this Source Note dated 26AUG2020. Please re-review source and correct page.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:43:03
User closed query 'Per Source; Please re-confirm if Lymph Nodes were Assessed, then would be "Yes" per Protocol.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:43:03
Query 'Per Source; Please re-confirm if Lymph Nodes were Assessed, then would be "Yes" per Protocol.' answered with 'please re-confirm query request. Per protocol only a symptom directed physical is required. Also per protocol, the axillary lymph nodes on the injection arm are to be examined. This patient like many others did not require a symptom direct PE' (Site from CRA).	Nicolle Mendez (b) (4)	24 Sep 2020 00:13:00
User opened query 'Per Source; Please re-confirm if Lymph Nodes were Assessed, then would be "Yes" per Protocol.' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 23:52:00
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 23:51:55
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:36:52
User entered 'No (N)'	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:51

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EAB) (1725)

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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:08:22
User closed query 'Visit 2 Source Notes Dated 26AUG2020 - Indicates that "Yes" Lymph Nodes were reviewed; Investigator Signed this Source Note dated 26AUG2020. Please re-review source and add Date of Examination = 26-AUG-2020' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:08:18
Query 'Visit 2 Source Notes Dated 26AUG2020 - Indicates that "Yes" Lymph Nodes were reviewed; Investigator Signed this Source Note dated 26AUG2020. Please re-review source and add Date of Examination = 26-AUG-2020' answered with 'completed' (Site from CRA).	Karen Mylerberg (b) (4)	01 Oct 2020 14:32:44
User entered '26 Aug 2020' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	01 Oct 2020 14:32:28
User opened query 'Visit 2 Source Notes Dated 26AUG2020 - Indicates that "Yes" Lymph Nodes were reviewed; Investigator Signed this Source Note dated 26AUG2020. Please re-review source and add Date of Examination = 26-AUG-2020' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:44:03
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 23:51:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:36:52
User entered empty.	Karen Mylerberg (b) (4)	06 Sep 2020 21:02:51

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4)	16 Sep 2020 22:37:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 20:02:26

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:32
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:02:26

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:37:32
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:02:26

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 20:02:26

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:32
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 20:02:26

US3112043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:32
User entered '12:45'	(b) (4), (b) (6)	26 Aug 2020 20:02:26

US3112043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered '26 Aug 2020 12:45'	System	26 Aug 2020 20:02:26

US3112043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:32
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	26 Aug 2020 20:02:26

US3112043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:32
User entered 'ONCE'	System	26 Aug 2020 20:02:26

US3112043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:13:17

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 20:02:26

US3112043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:45
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	06 Sep 2020 21:03:29

US3112043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:45
User entered '26 Aug 2020'	Karen Mylerberg (b) (4)	06 Sep 2020 21:03:29

US3112043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:45
User entered '11:35'	Karen Mylerberg (b) (4)	06 Sep 2020 21:03:29

US3112043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered '26 Aug 2020 11:35'	System	06 Sep 2020 21:03:29

US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:53
User entered '26 Aug 2020'	Karen Mylerberg (b) (4)	06 Sep 2020 21:03:47

US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	(b) (4) 06 Sep 2020 21:03:47

US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	06 Sep 2020 21:03:47

US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:17

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:53
User entered '11:56'	Karen Mylerberg (b) (4)	06 Sep 2020 21:03:47

US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered '26 Aug 2020 11:56'	System	06 Sep 2020 21:03:47

US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	(b) (4) 06 Sep 2020 21:03:47

US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:53
User entered 'No (N)'	Karen Mylerberg (b) (4)	06 Sep 2020 21:03:47

US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:37:53
User entered empty.	Karen Mylerberg (b) (4)	06 Sep 2020 21:03:47

US3112043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered empty.	System	06 Sep 2020 21:03:47

US3112043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:38:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 20:02:33

US3112043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'I'	System	26 Aug 2020 20:02:33

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:53:26', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '12034957-4748-47a6-84d3-b75842153e41' User entered 'Yes (Y)'	System	26 Aug 2020 20:54:07
	System	26 Aug 2020 20:54:07

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:53:52', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '12034957-4748-47a6-84d3-b75842153e41' User entered '97.4'	System	26 Aug 2020 20:54:07
	System	26 Aug 2020 20:54:07

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:53:57', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '12034957-4748-47a6-84d3-b75842153e41'	System	26 Aug 2020 20:54:07
User entered 'No (N)'	System	26 Aug 2020 20:54:07

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:06', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '12034957-4748-47a6-84d3-b75842153e41' User entered '26 Aug 2020 13:54'	System	26 Aug 2020 20:54:07
	System	26 Aug 2020 20:54:07

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '26 Aug 2020 13:05'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '26 Aug 2020 15:35'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:51:28', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7c8a9ec2-e688-4a91-ac39-88afd452ccf3' User entered 'Yes (Y)'	System	27 Aug 2020 03:52:03
	System	27 Aug 2020 03:52:03

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:51:40', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7c8a9ec2-e688-4a91-ac39-88afd452ccf3' User entered '97.6'	System	27 Aug 2020 03:52:03
	System	27 Aug 2020 03:52:03

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:51:46', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7c8a9ec2-e688-4a91-ac39-88afd452ccf3'	System	27 Aug 2020 03:52:03
User entered 'No (N)'	System	27 Aug 2020 03:52:03

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7c8a9ec2-e688-4a91-ac39-88afd452ccf3' User entered '26 Aug 2020 20:52'	System	27 Aug 2020 03:52:03
	System	27 Aug 2020 03:52:03

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '26 Aug 2020 16:30'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 2'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:01:53', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'a389884d-a112-4495-876e-e45850a8b78b' User entered 'Yes (Y)'	System	27 Aug 2020 23:02:15
	System	27 Aug 2020 23:02:15

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:02:03', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'a389884d-a112-4495-876e-e45850a8b78b' User entered '97.6'	System	27 Aug 2020 23:02:15
	System	27 Aug 2020 23:02:15

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:02:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'a389884d-a112-4495-876e-e45850a8b78b' User entered 'No (N)'	System	27 Aug 2020 23:02:15
	System	27 Aug 2020 23:02:15

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:02:12', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'a389884d-a112-4495-876e-e45850a8b78b' User entered '27 Aug 2020 16:02'	System	27 Aug 2020 23:02:15
	System	27 Aug 2020 23:02:15

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 3'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 4'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:12:47', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '77b4aff4-48bd-4e27-b8a6-f424228361fe' User entered 'Yes (Y)'	System	29 Aug 2020 22:13:25
	System	29 Aug 2020 22:13:25

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:13:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '77b4aff4-48bd-4e27-b8a6-f424228361fe' User entered '97.8'	System	29 Aug 2020 22:13:25
	System	29 Aug 2020 22:13:25

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:13:16', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '77b4aff4-48bd-4e27-b8a6-f424228361fe'	System	29 Aug 2020 22:13:25
User entered 'No (N)'	System	29 Aug 2020 22:13:25

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:13:19', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '77b4aff4-48bd-4e27-b8a6-f424228361fe' User entered '29 Aug 2020 15:13'	System	29 Aug 2020 22:13:25
	System	29 Aug 2020 22:13:25

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 5'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:05:35', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b401019b-9cf1-46b5-b7fd-c8cceb722a2' User entered 'Yes (Y)'	System	31 Aug 2020 05:06:06
	System	31 Aug 2020 05:06:06

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:05:49', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b401019b-9cf1-46b5-b7fd-c8cceb722a2' User entered '98.1'	System	31 Aug 2020 05:06:06
	System	31 Aug 2020 05:06:06

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:05:53', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b401019b-9cf1-46b5-b7fd-c8cceb722a2'	System	31 Aug 2020 05:06:06
User entered 'No (N)'	System	31 Aug 2020 05:06:06

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:04', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b401019b-9cf1-46b5-b7fd-c8cceb722a2'	System	31 Aug 2020 05:06:06
User entered '30 Aug 2020 22:06'	System	31 Aug 2020 05:06:06

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 6'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:13:20', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd070c1ff-4225-41ad-8765-62380d5a57dd' User entered 'Yes (Y)'	System	01 Sep 2020 04:13:39
	System	01 Sep 2020 04:13:39

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:13:28', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd070c1ff-4225-41ad-8765-62380d5a57dd' User entered '98.2'	System	01 Sep 2020 04:13:39
	System	01 Sep 2020 04:13:39

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:13:31', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd070c1ff-4225-41ad-8765-62380d5a57dd' User entered 'No (N)'	System	01 Sep 2020 04:13:39
	System	01 Sep 2020 04:13:39

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:13:37', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd070c1ff-4225-41ad-8765-62380d5a57dd' User entered '31 Aug 2020 21:13'	System	01 Sep 2020 04:13:39
	System	01 Sep 2020 04:13:39

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 7'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:11:58', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '57184d41-84f4-4eae-aaab-c6aec873611c' User entered 'Yes (Y)'	System	02 Sep 2020 01:12:17
	System	02 Sep 2020 01:12:17

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:12:06', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '57184d41-84f4-4eae-aaab-c6aec873611c' User entered '96.8'	System	02 Sep 2020 01:12:17
	System	02 Sep 2020 01:12:17

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:12:09', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '57184d41-84f4-4eae-aaab-c6aec873611c' User entered 'No (N)'	System	02 Sep 2020 01:12:17
	System	02 Sep 2020 01:12:17

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:12:15', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '57184d41-84f4-4eae-aaab-c6aec873611c' User entered '01 Sep 2020 18:12'	System	02 Sep 2020 01:12:17
	System	02 Sep 2020 01:12:17

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:49', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '24e16e97-200b-4d28-b6ec-34b5a0adcd99' User entered 'None (1)'	System	26 Aug 2020 20:55:08
	System	26 Aug 2020 20:55:08

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:53', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '24e16e97-200b-4d28-b6ec-34b5a0adcd99' User entered 'No (N)'	System	26 Aug 2020 20:55:08
	System	26 Aug 2020 20:55:08

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:56', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '24e16e97-200b-4d28-b6ec-34b5a0adcd99' User entered 'No (N)'	System	26 Aug 2020 20:55:08
	System	26 Aug 2020 20:55:08

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:59', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '24e16e97-200b-4d28-b6ec-34b5a0adcd99' User entered 'None (1)'	System	26 Aug 2020 20:55:08
	System	26 Aug 2020 20:55:08

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:55:02', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '24e16e97-200b-4d28-b6ec-34b5a0adcd99' User entered '26 Aug 2020 13:55'	System	26 Aug 2020 20:55:08
	System	26 Aug 2020 20:55:08

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '26 Aug 2020 13:05'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '26 Aug 2020 15:35'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:14', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'efbc5fc3-0618-4bd8-b8df-512d0f459c12'	System	27 Aug 2020 03:52:33
User entered 'None (1)'	System	27 Aug 2020 03:52:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:18', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'efbc5fc3-0618-4bd8-b8df-512d0f459c12'	System	27 Aug 2020 03:52:33
User entered 'No (N)'	System	27 Aug 2020 03:52:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:21', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'efbc5fc3-0618-4bd8-b8df-512d0f459c12'	System	27 Aug 2020 03:52:33
User entered 'No (N)'	System	27 Aug 2020 03:52:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:26', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'efbc5fc3-0618-4bd8-b8df-512d0f459c12'	System	27 Aug 2020 03:52:33
User entered 'None (1)'	System	27 Aug 2020 03:52:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:29', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'efbc5fc3-0618-4bd8-b8df-512d0f459c12'	System	27 Aug 2020 03:52:33
User entered '26 Aug 2020 20:52'	System	27 Aug 2020 03:52:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '26 Aug 2020 16:30'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 2'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:02:32', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '3825ae6a-ef3f-4e6f-b613-8ac5679d7bfa'	System	27 Aug 2020 23:03:20
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 23:03:20

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:02:40', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '3825ae6a-ef3f-4e6f-b613-8ac5679d7bfa' User entered 'No (N)'	System	27 Aug 2020 23:03:20
	System	27 Aug 2020 23:03:20

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:02:54', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '3825ae6a-ef3f-4e6f-b613-8ac5679d7bfa' User entered 'No (N)'	System	27 Aug 2020 23:03:20
	System	27 Aug 2020 23:03:20

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:01', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '3825ae6a-ef3f-4e6f-b613-8ac5679d7bfa'	System	27 Aug 2020 23:03:20
User entered 'None (1)'	System	27 Aug 2020 23:03:20

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:13', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '3825ae6a-ef3f-4e6f-b613-8ac5679d7bfa' User entered '27 Aug 2020 16:03'	System	27 Aug 2020 23:03:20
	System	27 Aug 2020 23:03:20

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 3'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 4'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:13:29', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0d148e9-7af3-4997-877f-a0c3e1578fbb' User entered 'None (1)'	System	29 Aug 2020 22:13:47
	System	29 Aug 2020 22:13:47

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:13:33', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0d148e9-7af3-4997-877f-a0c3e1578fbb' User entered 'No (N)'	System	29 Aug 2020 22:13:47
	System	29 Aug 2020 22:13:47

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:13:36', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0d148e9-7af3-4997-877f-a0c3e1578fbb' User entered 'No (N)'	System	29 Aug 2020 22:13:47
	System	29 Aug 2020 22:13:47

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:13:43', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0d148e9-7af3-4997-877f-a0c3e1578fbb' User entered 'None (1)'	System	29 Aug 2020 22:13:47
	System	29 Aug 2020 22:13:47

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:13:46', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f0d148e9-7af3-4997-877f-a0c3e1578fbb' User entered '29 Aug 2020 15:13'	System	29 Aug 2020 22:13:47
	System	29 Aug 2020 22:13:47

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 5'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:14', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '89402811-6934-41e6-b830-d29b92db1bd0'	System	31 Aug 2020 05:06:29
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 05:06:29

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:17', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '89402811-6934-41e6-b830-d29b92db1bd0' User entered 'No (N)'	System	31 Aug 2020 05:06:29
	System	31 Aug 2020 05:06:29

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:20', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '89402811-6934-41e6-b830-d29b92db1bd0' User entered 'No (N)'	System	31 Aug 2020 05:06:29
	System	31 Aug 2020 05:06:29

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:24', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '89402811-6934-41e6-b830-d29b92db1bd0' User entered 'None (1)'	System	31 Aug 2020 05:06:29
	System	31 Aug 2020 05:06:29

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:27', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '89402811-6934-41e6-b830-d29b92db1bd0' User entered '30 Aug 2020 22:06'	System	31 Aug 2020 05:06:29
	System	31 Aug 2020 05:06:29

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 6'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:13:46', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '63c1d594-79b8-4a41-8129-284ab1f0ed37'	System	01 Sep 2020 04:14:22
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 04:14:22

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:13:52', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '63c1d594-79b8-4a41-8129-284ab1f0ed37' User entered 'No (N)'	System	01 Sep 2020 04:14:22
	System	01 Sep 2020 04:14:22

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:13:57', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '63c1d594-79b8-4a41-8129-284ab1f0ed37' User entered 'No (N)'	System	01 Sep 2020 04:14:22
	System	01 Sep 2020 04:14:22

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:01', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '63c1d594-79b8-4a41-8129-284ab1f0ed37' User entered 'None (1)'	System	01 Sep 2020 04:14:22
	System	01 Sep 2020 04:14:22

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:21', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '63c1d594-79b8-4a41-8129-284ab1f0ed37' User entered '31 Aug 2020 21:14'	System	01 Sep 2020 04:14:22
	System	01 Sep 2020 04:14:22

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 7'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:12:28', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0b1ebb96-527f-412c-8309-645428d16eea' User entered 'None (1)'	System	02 Sep 2020 01:12:42
	System	02 Sep 2020 01:12:42

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:12:31', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0b1ebb96-527f-412c-8309-645428d16eea' User entered 'No (N)'	System	02 Sep 2020 01:12:42
	System	02 Sep 2020 01:12:42

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:12:34', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0b1ebb96-527f-412c-8309-645428d16eea' User entered 'No (N)'	System	02 Sep 2020 01:12:42
	System	02 Sep 2020 01:12:42

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:12:37', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0b1ebb96-527f-412c-8309-645428d16eea' User entered 'None (1)'	System	02 Sep 2020 01:12:42
	System	02 Sep 2020 01:12:42

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:12:39', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0b1ebb96-527f-412c-8309-645428d16eea' User entered '01 Sep 2020 18:12'	System	02 Sep 2020 01:12:42
	System	02 Sep 2020 01:12:42

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:19', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd9425f17-bca4-4310-9400-ebac3779b1bf' User entered 'None (0)'	System	26 Aug 2020 20:54:57
	System	26 Aug 2020 20:54:57

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:22', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd9425f17-bca4-4310-9400-ebac3779b1bf' User entered 'None (0)'	System	26 Aug 2020 20:54:57
	System	26 Aug 2020 20:54:57

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:24', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd9425f17-bca4-4310-9400-ebac3779b1bf' User entered 'None (0)'	System	26 Aug 2020 20:54:57
	System	26 Aug 2020 20:54:57

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:27', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd9425f17-bca4-4310-9400-ebac3779b1bf' User entered 'None (0)'	System	26 Aug 2020 20:54:57
	System	26 Aug 2020 20:54:57

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:30', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd9425f17-bca4-4310-9400-ebac3779b1bf' User entered 'None (0)'	System	26 Aug 2020 20:54:57
	System	26 Aug 2020 20:54:57

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:32', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd9425f17-bca4-4310-9400-ebac3779b1bf' User entered 'None (0)'	System	26 Aug 2020 20:54:57
	System	26 Aug 2020 20:54:57

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:35', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd9425f17-bca4-4310-9400-ebac3779b1bf' User entered 'No (N)'	System	26 Aug 2020 20:54:57
	System	26 Aug 2020 20:54:57

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T13:54:38', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'd9425f17-bca4-4310-9400-ebac3779b1bf' User entered '26 Aug 2020 13:54'	System	26 Aug 2020 20:54:57
	System	26 Aug 2020 20:54:57

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '26 Aug 2020 13:05'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '26 Aug 2020 15:35'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:38', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '889728ef-8b5d-4bf4-adf3-7375d83054ad' User entered 'None (0)'	System	27 Aug 2020 03:53:16
	System	27 Aug 2020 03:53:16

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:43', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '889728ef-8b5d-4bf4-adf3-7375d83054ad'	System	27 Aug 2020 03:53:16
User entered 'No interference with activity (1)'	System	27 Aug 2020 03:53:16

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:48', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '889728ef-8b5d-4bf4-adf3-7375d83054ad'	System	27 Aug 2020 03:53:16
User entered 'No interference with activity (1)'	System	27 Aug 2020 03:53:16

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:52:57', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '889728ef-8b5d-4bf4-adf3-7375d83054ad'	System	27 Aug 2020 03:53:16
User entered 'No interference with activity (1)'	System	27 Aug 2020 03:53:16

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:53:01', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '889728ef-8b5d-4bf4-adf3-7375d83054ad' User entered 'None (0)'	System	27 Aug 2020 03:53:16
	System	27 Aug 2020 03:53:16

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:53:03', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '889728ef-8b5d-4bf4-adf3-7375d83054ad' User entered 'None (0)'	System	27 Aug 2020 03:53:16
	System	27 Aug 2020 03:53:16

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:53:09', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '889728ef-8b5d-4bf4-adf3-7375d83054ad' User entered 'No (N)'	System	27 Aug 2020 03:53:16
	System	27 Aug 2020 03:53:16

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-26T20:53:13', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '889728ef-8b5d-4bf4-adf3-7375d83054ad' User entered '26 Aug 2020 20:53'	System	27 Aug 2020 03:53:16
	System	27 Aug 2020 03:53:16

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '26 Aug 2020 16:30'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 2'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:19', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'af36d5ff-e057-432d-8938-5b5fd34d34d0' User entered 'None (0)'	System	27 Aug 2020 23:03:48
	System	27 Aug 2020 23:03:48

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:27', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'af36d5ff-e057-432d-8938-5b5fd34d34d0'	System	27 Aug 2020 23:03:48
User entered 'No interference with activity (1)'	System	27 Aug 2020 23:03:48

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:30', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'af36d5ff-e057-432d-8938-5b5fd34d34d0'	System	27 Aug 2020 23:03:48
User entered 'No interference with activity (1)'	System	27 Aug 2020 23:03:48

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:35', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'af36d5ff-e057-432d-8938-5b5fd34d34d0' User entered 'None (0)'	System	27 Aug 2020 23:03:48
	System	27 Aug 2020 23:03:48

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:38', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'af36d5ff-e057-432d-8938-5b5fd34d34d0' User entered 'None (0)'	System	27 Aug 2020 23:03:48
	System	27 Aug 2020 23:03:48

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:40', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'af36d5ff-e057-432d-8938-5b5fd34d34d0' User entered 'None (0)'	System	27 Aug 2020 23:03:48
	System	27 Aug 2020 23:03:48

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:44', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'af36d5ff-e057-432d-8938-5b5fd34d34d0' User entered 'No (N)'	System	27 Aug 2020 23:03:48
	System	27 Aug 2020 23:03:48

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-27T16:03:47', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'af36d5ff-e057-432d-8938-5b5fd34d34d0' User entered '27 Aug 2020 16:03'	System	27 Aug 2020 23:03:48
	System	27 Aug 2020 23:03:48

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 3'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 4'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:14:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b851fdb5-4191-4696-a98a-6d9837483381' User entered 'None (0)'	System	29 Aug 2020 22:14:29
	System	29 Aug 2020 22:14:29

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:14:03', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b851fdb5-4191-4696-a98a-6d9837483381' User entered 'None (0)'	System	29 Aug 2020 22:14:29
	System	29 Aug 2020 22:14:29

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:14:09', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b851fdb5-4191-4696-a98a-6d9837483381' User entered 'None (0)'	System	29 Aug 2020 22:14:29
	System	29 Aug 2020 22:14:29

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:14:11', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b851fdb5-4191-4696-a98a-6d9837483381' User entered 'None (0)'	System	29 Aug 2020 22:14:29
	System	29 Aug 2020 22:14:29

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:14:13', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b851fdb5-4191-4696-a98a-6d9837483381' User entered 'None (0)'	System	29 Aug 2020 22:14:29
	System	29 Aug 2020 22:14:29

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:14:16', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b851fdb5-4191-4696-a98a-6d9837483381' User entered 'None (0)'	System	29 Aug 2020 22:14:29
	System	29 Aug 2020 22:14:29

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:14:23', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b851fdb5-4191-4696-a98a-6d9837483381' User entered 'No (N)'	System	29 Aug 2020 22:14:29
	System	29 Aug 2020 22:14:29

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-29T15:14:26', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b851fdb5-4191-4696-a98a-6d9837483381' User entered '29 Aug 2020 15:14'	System	29 Aug 2020 22:14:29
	System	29 Aug 2020 22:14:29

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 5'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:34', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6a7439d1-6d20-420d-88a9-5b83cfc20c56' User entered 'None (0)'	System	31 Aug 2020 05:07:01
	System	31 Aug 2020 05:07:01

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:37', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6a7439d1-6d20-420d-88a9-5b83cfc20c56' User entered 'None (0)'	System	31 Aug 2020 05:07:01
	System	31 Aug 2020 05:07:01

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:39', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6a7439d1-6d20-420d-88a9-5b83cfc20c56' User entered 'None (0)'	System	31 Aug 2020 05:07:01
	System	31 Aug 2020 05:07:01

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:41', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6a7439d1-6d20-420d-88a9-5b83cfc20c56' User entered 'None (0)'	System	31 Aug 2020 05:07:01
	System	31 Aug 2020 05:07:01

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:44', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6a7439d1-6d20-420d-88a9-5b83cfc20c56' User entered 'None (0)'	System	31 Aug 2020 05:07:01
	System	31 Aug 2020 05:07:01

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:45', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6a7439d1-6d20-420d-88a9-5b83cfc20c56' User entered 'None (0)'	System	31 Aug 2020 05:07:01
	System	31 Aug 2020 05:07:01

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:06:56', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6a7439d1-6d20-420d-88a9-5b83cfc20c56' User entered 'No (N)'	System	31 Aug 2020 05:07:01
	System	31 Aug 2020 05:07:01

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-30T22:07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6a7439d1-6d20-420d-88a9-5b83cfc20c56' User entered '30 Aug 2020 22:07'	System	31 Aug 2020 05:07:01
	System	31 Aug 2020 05:07:01

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 6'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:27', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f745e078-a452-4ba2-b29e-c832a3481a47' User entered 'None (0)'	System	01 Sep 2020 04:14:54
	System	01 Sep 2020 04:14:54

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:32', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f745e078-a452-4ba2-b29e-c832a3481a47' User entered 'None (0)'	System	01 Sep 2020 04:14:54
	System	01 Sep 2020 04:14:54

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:36', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f745e078-a452-4ba2-b29e-c832a3481a47' User entered 'None (0)'	System	01 Sep 2020 04:14:54
	System	01 Sep 2020 04:14:54

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:39', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f745e078-a452-4ba2-b29e-c832a3481a47'	System	01 Sep 2020 04:14:54
User entered 'No interference with activity (1)'	System	01 Sep 2020 04:14:54

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:42', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f745e078-a452-4ba2-b29e-c832a3481a47' User entered 'None (0)'	System	01 Sep 2020 04:14:54
	System	01 Sep 2020 04:14:54

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:45', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f745e078-a452-4ba2-b29e-c832a3481a47' User entered 'None (0)'	System	01 Sep 2020 04:14:54
	System	01 Sep 2020 04:14:54

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:49', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f745e078-a452-4ba2-b29e-c832a3481a47' User entered 'No (N)'	System	01 Sep 2020 04:14:54
	System	01 Sep 2020 04:14:54

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-08-31T21:14:51', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f745e078-a452-4ba2-b29e-c832a3481a47' User entered '31 Aug 2020 21:14'	System	01 Sep 2020 04:14:54
	System	01 Sep 2020 04:14:54

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	26 Aug 2020 20:02:26
User entered 'Day 7'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:12:49', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '96258d2d-77ec-4633-b79a-6c3e7a865b36' User entered 'None (0)'	System	02 Sep 2020 01:13:23
	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:13:01', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '96258d2d-77ec-4633-b79a-6c3e7a865b36' User entered 'None (0)'	System	02 Sep 2020 01:13:23
	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:13:03', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '96258d2d-77ec-4633-b79a-6c3e7a865b36'	System	02 Sep 2020 01:13:23
User entered 'No interference with activity (1)'	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:13:08', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '96258d2d-77ec-4633-b79a-6c3e7a865b36' User entered 'None (0)'	System	02 Sep 2020 01:13:23
	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:13:11', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '96258d2d-77ec-4633-b79a-6c3e7a865b36' User entered 'None (0)'	System	02 Sep 2020 01:13:23
	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:13:14', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '96258d2d-77ec-4633-b79a-6c3e7a865b36' User entered 'None (0)'	System	02 Sep 2020 01:13:23
	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:13:17', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '96258d2d-77ec-4633-b79a-6c3e7a865b36' User entered 'No (N)'	System	02 Sep 2020 01:13:23
	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-01T18:13:20', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '96258d2d-77ec-4633-b79a-6c3e7a865b36' User entered '01 Sep 2020 18:13'	System	02 Sep 2020 01:13:23
	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:02:26

US3112043

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	02 Sep 2020 01:13:23
User entered 'Day 8'	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:13:17

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-02T12:01:57', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '76d34a7b-d6dd-483c-9e21-54510cc79b02' User entered 'None (0)'	System	02 Sep 2020 19:02:05
	System	02 Sep 2020 19:02:05

US3112043

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-02T12:02:02', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '76d34a7b-d6dd-483c-9e21-54510cc79b02' User entered '02 Sep 2020 12:02'	System	02 Sep 2020 19:02:05
	System	02 Sep 2020 19:02:05

US3112043

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 01:13:23

US3112043

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
Data entry locked.	System	01 Sep 2020 04:14:22
User entered 'Day 8'	System	01 Sep 2020 04:14:22

US3112043

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

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 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-02T12:02:22', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '2d6f6c65-1ee4-4262-9bd1-dd82ee8b975b' User entered 'No (N)'	System	02 Sep 2020 19:02:27
	System	02 Sep 2020 19:02:27

US3112043

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D24011F0-0F6E-4F7B-9694-6E8F6BE9BDEA)', Time: '2020-09-02T12:02:25', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '2d6f6c65-1ee4-4262-9bd1-dd82ee8b975b' User entered '02 Sep 2020 12:02'	System	02 Sep 2020 19:02:27
	System	02 Sep 2020 19:02:27

US3112043

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 04:14:22

US3112043

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:13:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:06:33
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 04:14:22

US3112043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
User closed query 'Per AE Source; Please add "AE - Cervical Radiculopathy to AE eCRF Page.'" (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:27:09
Query 'Per AE Source; Please add "AE - Cervical Radiculopathy to AE eCRF Page.'" answered with 'done' (Site from CRA).	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 15:17:51
User opened query 'Per AE Source; Please add "AE - Cervical Radiculopathy to AE eCRF Page.'" (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 22:48:56
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:38:48
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Sep 2020 01:27:34
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Sep 2020 01:27:16
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	03 Sep 2020 01:27:16

US3112043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:38:48
User entered '2 Sep 2020' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	03 Sep 2020 01:27:34
User entered empty.	Nicolle Mendez (b) (4)	03 Sep 2020 01:27:16

US3112043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:38:48
User entered 'Contact Made (CONTACT MADE)'	Nicolle Mendez (b) (4)	03 Sep 2020 01:27:16

US3112043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:38:48
User entered empty.	Nicolle Mendez (b) (4)	03 Sep 2020 01:27:16

US3112043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:31:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:38:55
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	03 Sep 2020 01:27:39

US3112043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'I'	System	03 Sep 2020 01:27:39

US3112043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:39:22
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	11 Sep 2020 00:08:17

US3112043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:39:22
User entered '10 Sep 2020'	Nicolle Mendez (b) (4)	11 Sep 2020 00:08:17

US3112043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:39:22
User entered 'Contact Made (CONTACT MADE)'	Nicolle Mendez (b) (4)	11 Sep 2020 00:08:17

US3112043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:39:22
User entered empty.	Nicolle Mendez (b) (4)	11 Sep 2020 00:08:17

US3112043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 22:39:47
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	11 Sep 2020 00:08:21

US3112043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'I'	System	11 Sep 2020 00:08:21

US3112043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:31:27
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:57

US3112043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:31:27
User entered '18 Sep 2020'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:57

US3112043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:31:27
User entered 'Contact Made (CONTACT MADE)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:57

US3112043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:31:27
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:57

US3112043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:31:41
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:33:01

US3112043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'I'	System	18 Sep 2020 21:33:01

US3112043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:37:33
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Oct 2020 18:44:50

US3112043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:37:33
User entered '23 Sep 2020'	Natalie Moy (b) (4)	08 Oct 2020 18:44:50

US3112043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:37:33
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	08 Oct 2020 18:44:50

US3112043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'VISIT3'	System	08 Oct 2020 18:44:50

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered '23 Sep 2020'	Natalie Moy (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered '9:45'	Natalie Moy (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered '23 Sep 2020 9:45'	System	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered '97.6' F	Natalie Moy (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered empty.	Natalie Moy (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered '55'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'bpm'	System	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered '16'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'breaths/min'	System	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered '106'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'mmHg'	System	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:19
User entered '61'	Natalie Moy (b) (4)	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'mmHg'	System	08 Oct 2020 18:46:03

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22

US3112043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22

US3112043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:39:34
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 18:46:10

US3112043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:34
User entered empty.	Natalie Moy (b) (4)	08 Oct 2020 18:46:10

US3112043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:39:26
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 18:46:24

US3112043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:26
User entered '23 Sep 2020'	Natalie Moy (b) (4)	08 Oct 2020 18:46:24

US3112043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:39:26
User entered '10:00'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 18:46:24

US3112043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered '23 Sep 2020 10:00'	System	08 Oct 2020 18:46:24

US3112043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:39:46
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Oct 2020 18:46:33

US3112043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'I'	System	08 Oct 2020 18:46:33

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 64'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 71'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 78'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:13:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 92'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 99'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:13:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:13:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:13:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 106'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:13:17

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered 'Day 113'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

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Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:13:17

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Please 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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

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Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14

US3112043

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 18:11:51

US3112043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:58:14
Data entry locked.	System	31 Jul 2020 18:11:51
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 18:11:51

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2020-12-28T16:29:39', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '4d969889-8a96-4686-bbfa-415b72bcb7fe' User entered 'No (N)'	System	29 Dec 2020 00:30:06
	System	29 Dec 2020 00:30:06

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2020-12-28T16:29:49', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '4d969889-8a96-4686-bbfa-415b72bcb7fe' User entered 'No (N)'	System	29 Dec 2020 00:30:06
	System	29 Dec 2020 00:30:06

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2020-12-28T16:30:03', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '4d969889-8a96-4686-bbfa-415b72bcb7fe' User entered '28 Dec 2020 16:30:03'	System	29 Dec 2020 00:30:06
	System	29 Dec 2020 00:30:06

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-06T18:00:17', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b610f35a-62ed-42c4-8c44-2d73873f0b29'	System	07 Jan 2021 02:00:43
User entered 'No (N)'	System	07 Jan 2021 02:00:43

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-06T18:00:27', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b610f35a-62ed-42c4-8c44-2d73873f0b29'	System	07 Jan 2021 02:00:43
User entered 'No (N)'	System	07 Jan 2021 02:00:43

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-06T18:00:40', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'b610f35a-62ed-42c4-8c44-2d73873f0b29'	System	07 Jan 2021 02:00:43
User entered '06 Jan 2021 18:00:40'	System	07 Jan 2021 02:00:43

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-10T11:28:22', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6428fed7-d169-4524-88d7-3d478dc57896'	System	10 Jan 2021 19:29:05
User entered 'No (N)'	System	10 Jan 2021 19:29:05

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-10T11:28:54', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6428fed7-d169-4524-88d7-3d478dc57896'	System	10 Jan 2021 19:29:05
User entered 'No (N)'	System	10 Jan 2021 19:29:05

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-10T11:29:02', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '6428fed7-d169-4524-88d7-3d478dc57896' User entered '10 Jan 2021 11:29:02'	System	10 Jan 2021 19:29:05
	System	10 Jan 2021 19:29:05

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-17T09:34:09', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7e6cb97d-b856-4972-a3f6-d3e04815ef71' User entered 'No (N)'	System	17 Jan 2021 17:34:25
	System	17 Jan 2021 17:34:25

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-17T09:34:18', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7e6cb97d-b856-4972-a3f6-d3e04815ef71'	System	17 Jan 2021 17:34:25
User entered 'No (N)'	System	17 Jan 2021 17:34:25

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-17T09:34:23', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7e6cb97d-b856-4972-a3f6-d3e04815ef71' User entered '17 Jan 2021 09:34:23'	System	17 Jan 2021 17:34:25
	System	17 Jan 2021 17:34:25

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-25T15:33:09', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7d3d67f3-6ef9-4251-8b16-ce0a2618400d' User entered 'No (N)'	System	25 Jan 2021 23:33:32

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-25T15:33:15', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7d3d67f3-6ef9-4251-8b16-ce0a2618400d' User entered 'No (N)'	System	25 Jan 2021 23:33:32

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-01-25T15:33:27', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7d3d67f3-6ef9-4251-8b16-ce0a2618400d' User entered '25 Jan 2021 15:33:27'	System	25 Jan 2021 23:33:32
	System	25 Jan 2021 23:33:32

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-02T11:52:16', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '9fcfc06e-d299-4676-90cb-216518249dd2'	System	02 Feb 2021 19:52:44
User entered 'No (N)'	System	02 Feb 2021 19:52:44

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-02T11:52:30', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '9fcfc06e-d299-4676-90cb-216518249dd2'	System	02 Feb 2021 19:52:44
User entered 'No (N)'	System	02 Feb 2021 19:52:44

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-02T11:52:37', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '9fcfc06e-d299-4676-90cb-216518249dd2' User entered '02 Feb 2021 11:52:37'	System	02 Feb 2021 19:52:44
	System	02 Feb 2021 19:52:44

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-07T09:51:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '43cb7834-2185-4cd2-a9bb-04232dae2567'	System	07 Feb 2021 17:51:25
User entered 'No (N)'	System	07 Feb 2021 17:51:25

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-07T09:51:09', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '43cb7834-2185-4cd2-a9bb-04232dae2567'	System	07 Feb 2021 17:51:25
User entered 'No (N)'	System	07 Feb 2021 17:51:25

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-07T09:51:23', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '43cb7834-2185-4cd2-a9bb-04232dae2567'	System	07 Feb 2021 17:51:25
User entered '07 Feb 2021 09:51:23'	System	07 Feb 2021 17:51:25

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-16T00:35:17', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66ca9633-f751-4aa2-a7be-ae9a18b1a5e2'	System	18 Feb 2021 23:52:56
User entered 'No (N)'	System	18 Feb 2021 23:52:56

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-16T00:35:20', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66ca9633-f751-4aa2-a7be-ae9a18b1a5e2'	System	18 Feb 2021 23:52:56
User entered 'No (N)'	System	18 Feb 2021 23:52:56

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-16T00:35:26', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '66ca9633-f751-4aa2-a7be-ae9a18b1a5e2' User entered '16 Feb 2021 00:35:26'	System	18 Feb 2021 23:52:56
	System	18 Feb 2021 23:52:56

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-21T14:15:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f91199ad-5e0a-4a62-a8e5-b7e3317035c3' User entered 'No (N)'	System	21 Feb 2021 22:15:15
	System	21 Feb 2021 22:15:15

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-21T14:15:07', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f91199ad-5e0a-4a62-a8e5-b7e3317035c3' User entered 'No (N)'	System	21 Feb 2021 22:15:15
	System	21 Feb 2021 22:15:15

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-21T14:15:11', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'f91199ad-5e0a-4a62-a8e5-b7e3317035c3' User entered '21 Feb 2021 14:15:11'	System	21 Feb 2021 22:15:15
	System	21 Feb 2021 22:15:15

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-28T00:26:37-08:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'c7ae88ad-c9e2-4af0-9155-393f7f199eb5' User entered 'No (N)'	System	28 Feb 2021 08:26:50
	System	28 Feb 2021 08:26:50

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-28T00:26:41-08:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'c7ae88ad-c9e2-4af0-9155-393f7f199eb5'	System	28 Feb 2021 08:26:50
User entered 'No (N)'	System	28 Feb 2021 08:26:50

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-02-28T00:26:48-08:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'c7ae88ad-c9e2-4af0-9155-393f7f199eb5'	System	28 Feb 2021 08:26:50
User entered '28 Feb 2021 08:26:48'	System	28 Feb 2021 08:26:50

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-07T20:06:35-08:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '87116a2a-25ca-437d-94be-3c92421d4378'	System	08 Mar 2021 04:06:58
User entered 'No (N)'	System	08 Mar 2021 04:06:58

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-07T20:06:43-08:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '87116a2a-25ca-437d-94be-3c92421d4378'	System	08 Mar 2021 04:06:58
User entered 'No (N)'	System	08 Mar 2021 04:06:58

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-07T20:06:52-08:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '87116a2a-25ca-437d-94be-3c92421d4378'	System	08 Mar 2021 04:06:58
User entered '07 Mar 2021 20:06:52'	System	08 Mar 2021 04:06:58

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-14T11:34:39-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '55366940-9765-4705-a05b-0e30da7e4bdc'	System	14 Mar 2021 18:36:17
User entered 'Yes (Y)'	System	14 Mar 2021 18:36:17

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-14T11:34:44-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '55366940-9765-4705-a05b-0e30da7e4bdc'	System	14 Mar 2021 18:36:17
User entered 'No (N)'	System	14 Mar 2021 18:36:17

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-14T11:34:50-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '55366940-9765-4705-a05b-0e30da7e4bdc'	System	14 Mar 2021 18:36:17
User entered 'No (N)'	System	14 Mar 2021 18:36:17

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-14T11:35:08-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '55366940-9765-4705-a05b-0e30da7e4bdc'	System	14 Mar 2021 18:36:17
User entered 'Yes (Y)'	System	14 Mar 2021 18:36:17

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Please 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-14T11:35:35-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '55366940-9765-4705-a05b-0e30da7e4bdc'	System	14 Mar 2021 18:36:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Mar 2021 18:36:17

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-14T11:36:00-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '55366940-9765-4705-a05b-0e30da7e4bdc'	System	14 Mar 2021 18:36:17
User entered '14 Mar 2021 11:36:00'	System	14 Mar 2021 18:36:17

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-24T15:51:58-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '54242486-ecde-4085-b95a-9a4f1a424f18' User entered 'No (N)'	System	24 Mar 2021 22:52:20
	System	24 Mar 2021 22:52:20

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-24T15:52:05-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '54242486-ecde-4085-b95a-9a4f1a424f18'	System	24 Mar 2021 22:52:20
User entered 'No (N)'	System	24 Mar 2021 22:52:20

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-24T15:52:12-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '54242486-ecde-4085-b95a-9a4f1a424f18' User entered '24 Mar 2021 15:52:12'	System	24 Mar 2021 22:52:20
	System	24 Mar 2021 22:52:20

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-28T17:24:59-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0dce74a3-a0d1-4167-80d8-f6c30a5cf8ed' User entered 'No (N)'	System	06 Apr 2021 02:57:23
	System	06 Apr 2021 02:57:23

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-28T17:25:12-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0dce74a3-a0d1-4167-80d8-f6c30a5cf8ed' User entered 'No (N)'	System	06 Apr 2021 02:57:23
	System	06 Apr 2021 02:57:23

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-28T17:25:16-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '0dce74a3-a0d1-4167-80d8-f6c30a5cf8ed' User entered '28 Mar 2021 17:25:16'	System	06 Apr 2021 02:57:23
	System	06 Apr 2021 02:57:23

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-05T19:57:27-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '172c544c-c0ff-420b-8a39-1f348ad3b11d'	System	06 Apr 2021 02:57:42
User entered 'No (N)'	System	06 Apr 2021 02:57:42

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-05T19:57:32-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '172c544c-c0ff-420b-8a39-1f348ad3b11d'	System	06 Apr 2021 02:57:42
User entered 'No (N)'	System	06 Apr 2021 02:57:42

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-05T19:57:39-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '172c544c-c0ff-420b-8a39-1f348ad3b11d'	System	06 Apr 2021 02:57:42
User entered '05 Apr 2021 19:57:39'	System	06 Apr 2021 02:57:42

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-11T16:46:35-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7bf336f7-c0ea-4b3f-a661-21b5c45ad730' User entered 'No (N)'	System	11 Apr 2021 23:46:45
	System	11 Apr 2021 23:46:45

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-11T16:46:39-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7bf336f7-c0ea-4b3f-a661-21b5c45ad730' User entered 'No (N)'	System	11 Apr 2021 23:46:45

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-11T16:46:43-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '7bf336f7-c0ea-4b3f-a661-21b5c45ad730'	System	11 Apr 2021 23:46:45
User entered '11 Apr 2021 16:46:43'	System	11 Apr 2021 23:46:45

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-18T16:27:37-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5877353c-a521-4953-b18e-df2eadcee7dc' User entered 'No (N)'	System	18 Apr 2021 23:27:48
	System	18 Apr 2021 23:27:48

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-18T16:27:40-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5877353c-a521-4953-b18e-df2eadcee7dc' User entered 'No (N)'	System	18 Apr 2021 23:27:48
	System	18 Apr 2021 23:27:48

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-18T16:27:43-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5877353c-a521-4953-b18e-df2eadcee7dc'	System	18 Apr 2021 23:27:48
User entered '18 Apr 2021 16:27:43'	System	18 Apr 2021 23:27:48

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-25T18:17:08-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'e5e29dd6-f6c3-4011-aad6-9889c0b9b812' User entered 'No (N)'	System	26 Apr 2021 01:17:26
	System	26 Apr 2021 01:17:26

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-25T18:17:11-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'e5e29dd6-f6c3-4011-aad6-9889c0b9b812' User entered 'No (N)'	System	26 Apr 2021 01:17:26
	System	26 Apr 2021 01:17:26

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-04-25T18:17:23-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: 'e5e29dd6-f6c3-4011-aad6-9889c0b9b812' User entered '25 Apr 2021 18:17:23'	System	26 Apr 2021 01:17:26
	System	26 Apr 2021 01:17:26

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-05-02T22:33:21-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '1b501910-3dc8-45e9-9f86-98621fe680dc' User entered 'No (N)'	System	03 May 2021 05:34:02
	System	03 May 2021 05:34:02

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Have you been exposed to someone with 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 (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-05-02T22:33:25-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '1b501910-3dc8-45e9-9f86-98621fe680dc' User entered 'No (N)'	System	03 May 2021 05:34:02

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-05-02T22:33:28-07:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '1b501910-3dc8-45e9-9f86-98621fe680dc'	System	03 May 2021 05:34:02
User entered '02 May 2021 22:33:28'	System	03 May 2021 05:34:02

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 10:58:14

US3112043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:13:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:58:14
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 10:58:14

US3112043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:13:17

[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 09:04:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-01T17:04:12-08:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5d2e85c1-899b-47c3-8fc7-32c58a07b5d4'	System	02 Mar 2021 01:04:24
User entered 'No (N)'	System	02 Mar 2021 01:04:24

US3112043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:13:17

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:04:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4D43B0E-91F4-41CE-BBDB-722580B8B2F7)', Time: '2021-03-01T17:04:21-08:00', User OID: 'PatientReportedOutcome (US3112043)', ODM File OID: '5d2e85c1-899b-47c3-8fc7-32c58a07b5d4' User entered '01 Mar 2021 17:04:21'	System	02 Mar 2021 01:04:24
	System	02 Mar 2021 01:04:24

US3112043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:25:32
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:57
User entered 'Yes (Y)'	Natalie Moy (b) (4)	20 Oct 2020 23:23:49

US3112043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:25:32
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:57
User entered '20 Oct 2020'	Natalie Moy (b) (4)	20 Oct 2020 23:23:49

US3112043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:25:32
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:57
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4)	20 Oct 2020 23:23:49

US3112043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:25:32
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:57
User entered empty.	Natalie Moy (b) (4)	20 Oct 2020 23:23:49

US3112043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:25:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:57
User entered 'Yes (Y)'	Natalie Moy (b) (4)	20 Oct 2020 23:23:53

US3112043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:23:22
User entered 'I'	System	20 Oct 2020 23:23:53

US3112043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:29:23
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	23 Nov 2020 23:00:10

US3112043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:29:23
User entered '23 Nov 2020'	Matthew Musikanth (b) (4)	23 Nov 2020 23:00:10

US3112043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:29:23
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	23 Nov 2020 23:00:10

US3112043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:29:23
User entered empty.	Matthew Musikanth (b) (4)	23 Nov 2020 23:00:10

US3112043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:29:28
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	23 Nov 2020 23:00:14

US3112043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered 'I'	System	23 Nov 2020 23:00:14

US3112043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:38:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Jan 2021 00:03:50

US3112043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:38:22
User entered '23 Dec 2020'	Karen Mylerberg (b) (4)	23 Jan 2021 00:03:50

US3112043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:38:22
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	23 Jan 2021 00:03:50

US3112043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:38:22
User entered empty.	Karen Mylerberg (b) (4)	23 Jan 2021 00:03:50

US3112043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:38:59
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Jan 2021 00:03:59

US3112043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered 'I'	System	23 Jan 2021 00:03:59

US3112043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:45:19
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Jan 2021 00:04:10

US3112043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:45:19
User entered '22 Jan 2021'	Karen Mylerberg (b) (4)	23 Jan 2021 00:04:10

US3112043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:45:19
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	23 Jan 2021 00:04:10

US3112043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:45:19
User entered empty.	Karen Mylerberg (b) (4)	23 Jan 2021 00:04:10

US3112043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:45:23
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Jan 2021 00:04:19

US3112043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered '1'	System	23 Jan 2021 00:04:19

US3112043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:47:18
User entered 'Yes (Y)'	Brenda Grande (b) (4)	23 Feb 2021 16:22:39

US3112043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:47:18
User closed query 'Per GCL Lab Recon: Immuno: Sample dated 22 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:04:50
Query 'Per GCL Lab Recon: Immuno: Sample dated 22 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' answered with 'data has been added to edc' (Site from DM).	Brenda Grande (b) (4)	09 Mar 2021 18:49:10
User opened query 'Per GCL Lab Recon: Immuno: Sample dated 22 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 17:56:16
User entered '22 Feb 2021'	Brenda Grande (b) (4)	23 Feb 2021 16:22:39

US3112043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:47:18
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4)	23 Feb 2021 16:22:39

US3112043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered 'VISIT4'	System	23 Feb 2021 16:22:39

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User entered '22 Feb 2021'	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User entered '10:24'	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered '22 Feb 2021 10:24'	System	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User entered '97.8' F	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User entered '79'	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered 'bpm'	System	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User entered '14'	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered 'breaths/min'	System	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User entered '84'	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered 'mmHg'	System	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:46:13
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 07:21:22
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 20:48:16
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		30 Mar 2021 20:47:43
User entered '50'	(b) (4), (b) (6)	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered 'mmHg'	System	30 Mar 2021 20:47:43

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26

US3112043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:13:17

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26

US3112043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:48:42
User entered 'Yes (Y)'	Brenda Grande (b) (4)	23 Feb 2021 16:22:59

US3112043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:13:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:48:42
User entered '22 Feb 2021'	Brenda Grande (b) (4)	23 Feb 2021 16:22:59

US3112043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:49:05
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Mar 2021 19:58:04

US3112043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:49:05
User entered '22 Feb 2021'	Brenda Grande (b) (4)	08 Mar 2021 19:58:04

US3112043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:49:05
User entered '10:51'	Brenda Grande (b) (4)	08 Mar 2021 19:58:04

US3112043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered '22 Feb 2021 10:51'	System	08 Mar 2021 19:58:04

US3112043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:49:12
User entered 'Yes (Y)'	Brenda Grande (b) (4)	23 Feb 2021 16:23:02

US3112043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:35:26
User entered '1'	System	23 Feb 2021 16:23:02

US3112043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:31:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:35:23
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	18 Mar 2021 19:56:22

US3112043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:31:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:35:23
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 11:03:34
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'completed on this date.' (Site from System).	Matthew Musikanth (b) (4)	18 Mar 2021 19:56:44
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Mar 2021 19:56:22
User entered '26 Feb 2021'	Matthew Musikanth (b) (4)	18 Mar 2021 19:56:22

US3112043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:31:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:35:23
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	18 Mar 2021 19:56:22

US3112043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:31:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:38:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:35:23
User entered empty.	Matthew Musikanth (b) (4)	18 Mar 2021 19:56:22

US3112043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:31:49
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:37:50
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 17:19:49

US3112043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:31:49
User entered 'I'	System	23 Apr 2021 17:19:49

US3112043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 17:20:03

US3112043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
User entered '23 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 17:20:03

US3112043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Apr 2021 17:20:03

US3112043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:13:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 17:20:03

US3112043

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 17:20:08

US3112043

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:13:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 17:20:08

US3112043

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

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:41:35
User entered 'Yes (Y)'	Natalie Moy (b) (4)	06 Jan 2021 22:54:31

US3112043

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

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:41:35
User entered '6 Jan 2021'	Natalie Moy (b) (4)	06 Jan 2021 22:54:31

US3112043

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

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:41:35
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	06 Jan 2021 22:54:31

US3112043

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

Form: Visit Date

Generated On: 09 Jun 2021 15:13:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 22:54:31

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:18
User entered '6 Jan 2021'	Natalie Moy (b) (4)	06 Jan 2021 22:54:44

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:18
User entered '0'	Brenda Grande (b) (4)	11 Mar 2021 17:56:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:59:17

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:18
User entered 'Yes (Y)'	Natalie Moy (b) (4)	06 Jan 2021 22:54:44

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:18
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brenda Grande (b) (4)	11 Mar 2021 17:56:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:59:17

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:18
User entered '6 Jan 2021'	Natalie Moy (b) (4)	06 Jan 2021 22:54:44

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:18
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Moy (b) (4)	06 Jan 2021 22:54:44

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:18
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 05:51:49
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Moy (b) (4)	06 Jan 2021 22:54:44

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:18
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 05:51:49
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Moy (b) (4)	06 Jan 2021 22:54:44

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:18
User entered 'No (N)'	Natalie Moy (b) (4)	06 Jan 2021 22:54:44

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User entered empty.	System	06 Jan 2021 22:54:44

US3112043

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

Form: Unblinding

Generated On: 09 Jun 2021 15:13:17

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User entered empty.	System	06 Jan 2021 22:54:44

US3112043

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:39
User entered 'Yes (Y)'	Natalie Moy (b) (4)	06 Jan 2021 22:54:53

US3112043

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:39
User entered '6 Jan 2021'	Natalie Moy (b) (4)	06 Jan 2021 22:54:53

US3112043

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:39
User entered '13:55'	Natalie Moy (b) (4)	06 Jan 2021 22:54:53

US3112043

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:13:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User entered '6 Jan 2021 13:55'	System	06 Jan 2021 22:54:53

US3112043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:13:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:47
User entered 'Yes (Y)'	Natalie Moy (b) (4)	06 Jan 2021 22:55:01

US3112043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:13:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:47
User entered '6 Jan 2021'	Natalie Moy (b) (4)	06 Jan 2021 22:55:01

US3112043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:13:17

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:44:47
User entered '13:59'	Natalie Moy (b) (4)	06 Jan 2021 22:55:01

US3112043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:13:17

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:43:53
User entered '6 Jan 2021 13:59'	System	06 Jan 2021 22:55:01

US3112043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:13:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:43:21
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:53
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:16
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 18:33:24
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:33:16
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:31:04

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User closed query 'Please re-confirm with Subject, if there is a Medical History of "CERVICAL RADICULOPATHY", and if condition should be added to Medical History eCRF Page.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:15:39
Query 'Please re-confirm with Subject, if there is a Medical History of "CERVICAL RADICULOPATHY", and if condition should be added to Medical History eCRF Page.' answered with 'per progress note written by investigator this is a new condition.' (Site from CRA).	Karen Mylerberg (b) (4)	01 Oct 2020 14:38:19
User opened query 'Please re-confirm with Subject, if there is a Medical History of "CERVICAL RADICULOPATHY", and if condition should be added to Medical History eCRF Page.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:34:40
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:33:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:33:50
Data point term sent to Coder	System	18 Sep 2020 21:32:49
User entered 'cervical radiculopathy'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'No (N)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'No (N)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'No (N)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '10 Sep 2020'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User entered empty.	System	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'No (N)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	30 Sep 2020 15:21:27
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '17 Sep 2020' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	30 Sep 2020 15:21:27
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User entered empty.	System	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'No (N)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '0'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '0'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '0'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '0'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '0'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '0'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'Not Related (NOT RELATED)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'Not Related (NOT RELATED)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'Not Applicable (NOT APPLICABLE)'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'I'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '0'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered '0'	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	30 Sep 2020 15:21:27
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:19:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 15:19:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	30 Sep 2020 15:19:47
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:32:41
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:43:08
User entered empty.	Nicolle Mendez (b) (4)	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User entered '0'	System	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53
User entered '0'	System	18 Sep 2020 21:32:41

US3112043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:13:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:29:53

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:43:20
User entered	System	16 Mar 2021 13:43:16
'USA-US062-2021-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	16 Mar 2021 13:43:16

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 08:56:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 08:56:51
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 22:06:25
User entered 'Diverticulitis with spontaneous resolution' reason for change: Data Entry Error	Matthew Musikanth	15 Mar 2021 22:06:11
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:40:41
User entered 'Gastrointestinal Bleeding (Not otherwise specified)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'Yes (Y)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'No (N)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'No (N)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '09 Mar 2021'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered empty.	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 21:39:45

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'No (N)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:50
DataPoint Un-verified.	Matthew Musikanth	13 Apr 2021 17:13:40
	(b) (4)	
User entered '13 Mar 2021' reason for change: Data Entry Error	Matthew Musikanth	13 Apr 2021 17:13:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '12 Mar 2021'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered empty.	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 21:39:45

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'Yes (Y)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '0'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '0'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'I'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '09 Mar 2021'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
	(b) (4), (b) (6)	14 Apr 2021 17:48:10
User closed query 'PV Query: Discharge date was reported as 12 Mar 2021, but medical records show 13 Mar 2021. Please review and reconcile accordingly. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:38
Query 'PV Query: Discharge date was reported as 12 Mar 2021, but medical records show 13 Mar 2021. Please review and reconcile accordingly. ' answered with 'Updated to reflect discharge date found in medical records instead of patient report. ' (Site from Safety). DataPoint Un-verified.	Matthew Musikanth (b) (4)	13 Apr 2021 17:14:40
User entered '13 Mar 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	13 Apr 2021 17:13:40
User opened query 'PV Query: Discharge date was reported as 12 Mar 2021, but medical records show 13 Mar 2021. Please review and reconcile accordingly. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 12:23:15
	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '12 Mar 2021'	Matthew Musikanth (b) (4)	15 Mar 2021 21:39:45

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'No (N)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered empty.	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '0'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '0'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '0'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	15 Mar 2021 21:39:45

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

None

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:46:29
	(b) (4)	
DataPoint Un-verified.	Matthew Musikanth	18 Mar 2021 22:23:54
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Matthew Musikanth	18 Mar 2021 22:23:54
	(b) (4)	
User closed query 'Please clarify. Source indicates action of conmeds, Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 18:11:02
	(b) (4)	
Query 'Please clarify. Source indicates action of conmeds, Please confirm and update as necessary.' answered with 'Conmed clarified for separate, congruent AE ' (Site from CRA).	Matthew Musikanth	18 Mar 2021 18:00:35
	(b) (4)	
User opened query 'Please clarify. Source indicates action of conmeds, Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:55:09
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
	(b) (4)	
User entered '1'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:46:31
DataPoint Un-verified.	Matthew Musikanth	18 Mar 2021 22:23:54
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Matthew Musikanth	18 Mar 2021 22:23:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '0'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered '0'	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	15 Mar 2021 21:39:45

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered empty.	Matthew Musikanth	15 Mar 2021 21:39:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
User closed query 'PV Query: Please consider whether the gastrointestinal bleeding and acute blood loss anemia requiring transfusion noted in the medical records meet criteria for AE/SAE reporting and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 17:48:15
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 17:48:13
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? ' answered with 'Patient was discharged after being monitored and diagnostics complete. Discharge upon resolution and patient stable on diet. ' (Site from Safety).	Matthew Musikanth (b) (4)	13 Apr 2021 17:15:55
Query 'PV Query: Please consider whether the gastrointestinal bleeding and acute blood loss anemia requiring transfusion noted in the medical records meet criteria for AE/SAE reporting and update report if appropriate. ' answered with 'All the same event reported. Diverticulitis with spontaneous resolution is the most updated diagnosis. ' (Site from Safety).	Matthew Musikanth (b) (4)	13 Apr 2021 17:03:20
User opened query 'PV Query: Please consider whether the gastrointestinal bleeding and acute blood loss anemia requiring transfusion noted in the medical records meet criteria for AE/SAE reporting and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:23:52
Query 'Please consider whether the gastrointestinal bleeding and acute blood loss anemia requiring transfusion noted in the medical records meet criteria for AE/SAE reporting and update report if appropriate. ' canceled (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:23:38
User opened query 'Please consider whether the gastrointestinal bleeding and acute blood loss anemia requiring transfusion noted in the medical records meet criteria for AE/SAE reporting and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:23:36

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:23:25
User closed query 'PV Query: Please provide any 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)	06 Apr 2021 15:03:27
User closed query 'PV Query: Did the subject have a medical history of diverticulitis? Was the SAE considered a worsening of the subject's medical history of diverticulitis?' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:03:24
User closed 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)	06 Apr 2021 15:03:22
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.' answered with 'Sent. ' (Site from Safety).	Matthew Musikanth (b) (4)	05 Apr 2021 18:28:27
Query 'PV Query: Please provide any 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 other than blood infusion included in conmeds.' (Site from Safety).	Matthew Musikanth (b) (4)	05 Apr 2021 16:59:09

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Did the subject have a medical history of diverticulitis? Was the SAE considered a worsening of the subject's medical history of diverticulitis?' answered with 'no prev. med hx of diverticulitis. ' (Site from Safety).	Matthew Musikanth (b) (4)	05 Apr 2021 16:58:51
User closed 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)	29 Mar 2021 15:27:21
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.' answered with 'pcr test performed subject is negative ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	26 Mar 2021 18:49:03
User opened query 'PV Query: Please provide any treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:20:02
User opened query 'PV Query: Did the subject have a medical history of diverticulitis? Was the SAE considered a worsening of the subject's medical history of diverticulitis?' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:19:50
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)	19 Mar 2021 20:19:38
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)	19 Mar 2021 20:19:23

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 23:52:44
User entered 'Pt. woke up morning of 09Mar2021 and noticed blood with bowel movements. Continued bleeding prompted patient to present at ED. After diagnostics at hospital, no cause determined and bleeding spontaneously resolved. Patient discharge day after. Total of 4 days spent in hospital.'	Matthew Musikanth (b) (4)	15 Mar 2021 21:39:45

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 21:39:45

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 21:39:45

US3112043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:13:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 21:39:45

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal mucosal dystrophies and secretion disorders, PT: Barrett's oesophagus, LLT: Barrett's esophagus - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 23:21:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 23:21:37
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 23:20:28
User entered 'Barretts Esophagus'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'Yes (Y)'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'No (N)'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'No (N)'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered '10 Mar 2021'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered empty.	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 23:19:46

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'Yes (Y)'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered empty.	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered empty.	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 23:19:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Matthew Musikanth (b) (4)	15 Mar 2021 23:19:46

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'No (N)'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered '0'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered '0'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered '0'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered empty.	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered empty.	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered empty.	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered empty.	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered '0'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered '0'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered '0'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered '0'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'I'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered '0'	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Musikanth (b) (4)	15 Mar 2021 23:19:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered empty.	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered empty.	Matthew Musikanth	15 Mar 2021 23:19:46
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 23:19:46

US3112043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:13:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 23:19:46

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
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)	18 Mar 2021 16:25:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 16:25:39
	(b) (4)	
Data point term sent to Coder	System	18 Mar 2021 16:24:41
User entered 'right knee pain'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'Yes (Y)'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'No (N)'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'No (N)'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	21 Apr 2021 20:58:53
Comment added 'Can confirm that day is unknown, so 'UN' is correct. Please close query.'	(b) (4), (b) (6)	20 Apr 2021 20:58:43
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:52:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Apr 2021 17:50:44
User entered 'un Dec 2020' (non-conformant).	Brenda Grande (b) (4)	08 Apr 2021 17:50:44
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Apr 2021 18:06:40
DataPoint Un-verified.	Brenda Grande (b) (4)	01 Apr 2021 18:06:40
	(b) (4)	
User entered '1 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4)	01 Apr 2021 18:06:40
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Mar 2021 16:24:36
User entered 'un Dec 2020' (non-conformant).	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered empty.	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 16:24:36

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
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. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 03:40:41
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. ' answered with 'per subject AE is still ongoing' (Site from DM).	Brenda Grande (b) (4)	01 Apr 2021 18:07:23
	(b) (4)	
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. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:07:22
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	18 Mar 2021 16:24:36

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered empty.	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered empty.	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 16:24:36

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'No (N)'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered '0'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered '0'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered '0'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered empty.	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered empty.	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered empty.	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered empty.	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered '0'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered '0'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered '0'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered '0'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'I'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered '0'	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Musikanth (b) (4)	18 Mar 2021 16:24:36

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered empty.	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:51
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:14
User entered empty.	Matthew Musikanth	18 Mar 2021 16:24:36
	(b) (4)	

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 16:24:36

US3112043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:13:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Mar 2021 16:24:36

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:13:17

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:43:21
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:40:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 17:53:35

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 18:03:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 18:03:19
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 18:02:29
User entered 'Tamsulosin'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'BPH'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '0.4'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:30:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:02:04
User entered 'UN UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:02:04

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 11:46:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Sep 2020 11:46:47
Data point term sent to Coder	System	18 Sep 2020 21:35:59
Coding entries removed.	Nicolle Mendez (b) (4)	18 Sep 2020 21:35:56
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 18:59:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 18:59:24
Data point term sent to Coder	System	20 Aug 2020 18:03:32
User entered 'Lasix'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:44:37
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication to include the specific location of PEDAL EDEMA (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 14:39:29
Query 'Per DM CLR: Please review the indication to include the specific location of PEDAL EDEMA (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' answered with 'updated to match medical history term' (Site from DM).	Nicolle Mendez (b) (4)	18 Sep 2020 21:36:32
DataPoint Un-verified.	Nicolle Mendez (b) (4)	18 Sep 2020 21:35:56
	(b) (4), (b) (6)	
User entered 'bilateral lower extremity pedal edema' reason for change: Data Entry Error	Nicolle Mendez (b) (4)	18 Sep 2020 21:35:56
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
	(b) (4), (b) (6)	
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)	14 Sep 2020 15:35:04
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)	14 Sep 2020 15:30:30
	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Please review the indication to include the specific location of PEDAL EDEMA (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 15:28:33
	(b) (4), (b) (6)	
User entered 'Pedal Edema'	(b) (4), (b) (6)	20 Aug 2020 18:02:47
	(b) (4), (b) (6)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '20'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:07:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:30:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:02:47
User entered 'UN UNK 1995'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:07:40
User entered '1'	System	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:07:40
User entered '1'	System	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:07:40
User entered '804 (804)'	System	20 Aug 2020 18:02:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:04:18
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Aug 2020 18:04:18
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 18:03:34
User entered 'Allopurinol'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Gout'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '300'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:30:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:03:24
User entered 'UN UNK 1995'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:03:24

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:05:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:05:33
Data point term sent to Coder User entered 'Lisinopril'	System (b) (4), (b) (6)	20 Aug 2020 18:04:39 20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'HTN'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '40' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:07:23
User entered '300'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:30:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:04:21
User entered 'UN UNK 1995'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:04:21

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: PYRIMIDINE DERIVATIVES, PRODUCT: MINOXIDIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 05:04:14
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 05:04:14
Data point term sent to Coder	System	20 Aug 2020 18:05:40
User entered 'Minoxidil'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'HTN'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '5'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:30:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:05:03
User entered 'UN UNK 1995'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:57:48
DataPoint Un-verified.	Matthew Musikanth	18 Mar 2021 22:53:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Mar 2021 22:53:16
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:57:50
DataPoint Un-verified.	Matthew Musikanth	18 Mar 2021 22:53:16
User entered '01 Feb 2021' reason for change: Data Entry Error	Matthew Musikanth	18 Mar 2021 22:53:16
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User entered empty.	System	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User entered empty.	System	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:38
User entered empty.	System	20 Aug 2020 18:05:03

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 18:07:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 18:07:19
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 18:06:42
User entered 'Claritin'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '10'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:30:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:05:44
User entered 'UN UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:05:44

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 18:08:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 18:08:23
Data point term sent to Coder	System	20 Aug 2020 18:07:43
User entered 'Atenolol'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'HTN'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '100'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:19
DataPoint Un-verified.	Matthew Musikanth (b) (4)	25 Mar 2021 16:10:34
User entered 'UN UNK 1995' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	25 Mar 2021 16:10:34
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:30:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:06:51
User entered 'UN UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:15
DataPoint Un-verified.	Matthew Musikanth	25 Mar 2021 16:11:01
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth	25 Mar 2021 16:11:01
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:17
DataPoint Un-verified.	Matthew Musikanth	25 Mar 2021 16:11:01
User entered '01 Feb 2021' reason for change: Data Entry Error	Matthew Musikanth	25 Mar 2021 16:11:01
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 22:46:29
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User entered empty.	System	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User entered empty.	System	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:44
User entered empty.	System	20 Aug 2020 18:06:51

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
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)	15 Mar 2021 23:23:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 23:23:37
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 23:22:29
User entered 'Pantoprazole'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered 'No (N)'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered 'Barrett's Esophagus'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered '40'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered 'mg (mg)'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered empty.	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered 'twice daily (BID)'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered empty.	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered 'Oral (ORAL)'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered empty.	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered '13 Mar 2021'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered '0'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered 'Yes (Y)'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered empty.	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:48:58
User entered 'No (N)'	Matthew Musikanth	15 Mar 2021 23:21:57
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Mar 2021 23:21:57

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 23:21:57

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Mar 2021 23:21:57

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 23:35:42
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 Mar 2021 23:35:42
Data point term sent to Coder	System	15 Mar 2021 23:34:49
User entered 'atenolol'	Natalie Moy (b) (4) (b) (4)	15 Mar 2021 23:33:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered 'No (N)'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered 'hypertension'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered '25' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	25 Mar 2021 16:11:35
User entered '100'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered 'mg (mg)'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered empty.	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered 'once daily (QD)'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered empty.	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered 'Oral (ORAL)'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered empty.	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered '2 Feb 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	25 Mar 2021 16:11:35
User entered 'un UNK 1995'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered '0'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	25 Mar 2021 16:11:35
User entered 'No (N)'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	25 Mar 2021 16:11:35
User entered '01 Feb 2021'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:36
User entered 'No (N)'	Natalie Moy (b) (4)	15 Mar 2021 23:33:47
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 23:33:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 23:33:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Mar 2021 23:33:47

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 02 FEB 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). Query 'Per DM CLR: this Con Med was added/ had dose increased on 02 FEB 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'no worsening of hypertension reported' (Site from DM). User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 02 FEB 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 03:17:40
DataPoint Verified.	(b) (4), (b) (6)	28 Mar 2021 07:17:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: PYRIMIDINE DERIVATIVES, PRODUCT: MINOXIDIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 23:35:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 23:35:40
Data point term sent to Coder	System	15 Mar 2021 23:34:47
User entered 'minoxidil'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered 'No (N)'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered 'hypertension'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered '5'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered 'mg (mg)'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered empty.	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered 'twice daily (BID)'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered empty.	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered 'Oral (ORAL)'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered empty.	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered '02 Feb 2021'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered '0'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered 'Yes (Y)'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered empty.	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:58:24
User entered 'No (N)'	Natalie Moy (b) (4)	15 Mar 2021 23:34:42
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Mar 2021 23:34:42

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 23:34:42

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Mar 2021 23:34:42

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 09:55:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 09:55:31
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
Data point term sent to Coder	System	15 Mar 2021 23:42:52
User entered 'steroid injection'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'No (N)'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'right knee pain'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'I'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'Other (OTHER)'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'injection'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'once (ONCE)'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered empty.	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'Other (OTHER)'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'intrajoint'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'un Dec 2020'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered '0'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'No (N)'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'un Dec 2020'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:51:43
User entered 'No (N)'	Natalie Moy (b) (4)	15 Mar 2021 23:42:45
	(b) (4)	

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 23:42:45

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 23:42:45

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 23:42:45

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User coded data point as ATC: VARIOUS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: BLOOD TRANSFUSION, AUXILIARY PRODUCTS, PRODUCT: BLOOD TRANSFUSION, AUXILIARY PRODUCTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 07:24:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 07:24:58
Data point term sent to Coder	System	18 Mar 2021 22:23:35
User entered 'BLood Transfusion'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered 'Diverticulitis'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered 'I'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered 'unit'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered empty.	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered empty.	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered '09 Mar 2021'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered '0'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered '09 Mar 2021'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:48:41
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User entered empty.	System	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User entered empty.	System	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:13:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:25:52
User entered empty.	System	18 Mar 2021 22:22:49

US3112043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:13:17

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:31:53
User entered 'No (N)'	Brenda Grande (b) (4)	18 Feb 2021 15:48:44
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'USA-US062-2021-MRNA-1273-P301000012'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Todd'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Todd'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Simmons'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Simmons'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '9040 Friars Road Suite 540'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '9040 Friars Rd. Suite 540'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'San Diego'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'San Diego'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'CA'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'California'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '92108'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '92108'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'US'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Apr 2021 17:48:43
User entered '4'	System	29 Mar 2021 15:28:30
User entered '3'	System	19 Mar 2021 16:03:12
User entered '2'	System	19 Mar 2021 14:59:47
User entered '1'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'USA-US062-2021-MRNA-1273-P301000012'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Todd'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Todd'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Simmons'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Simmons'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '9040 Friars Road Suite 540'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '9040 Friars Rd. Suite 540'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'San Diego'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'San Diego'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'CA'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'California'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '92108'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '92108'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'US'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Apr 2021 17:48:43
User entered '4'	System	29 Mar 2021 15:28:30
User entered '3'	System	19 Mar 2021 16:03:12
User entered '2'	System	19 Mar 2021 14:59:47
User entered '1'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:13:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '16/Mar/2021 09:43'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:13:17

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.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'USA-US062-2021-MRNA-1273-P301000012'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Todd'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Todd'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Simmons'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Simmons'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '9040 Friars Road Suite 540'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '9040 Friars Rd. Suite 540'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'San Diego'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'San Diego'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'CA'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'California'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '92108'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '92108'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'US'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Apr 2021 17:48:43
User entered '4'	System	29 Mar 2021 15:28:30
User entered '3'	System	19 Mar 2021 16:03:12
User entered '2'	System	19 Mar 2021 14:59:47
User entered '1'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:13:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
User entered '19/Mar/2021 09:59'	System	19 Mar 2021 14:59:47

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:13:17

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.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 14:59:47

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'USA-US062-2021-MRNA-1273-P301000012'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Todd'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Todd'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Simmons'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Simmons'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '9040 Friars Road Suite 540'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '9040 Friars Rd. Suite 540'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'San Diego'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'San Diego'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'CA'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'California'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '92108'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '92108'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'US'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Apr 2021 17:48:43
User entered '4'	System	29 Mar 2021 15:28:30
User entered '3'	System	19 Mar 2021 16:03:12
User entered '2'	System	19 Mar 2021 14:59:47
User entered '1'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:13:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
User entered '19/Mar/2021 11:03'	System	19 Mar 2021 16:03:12

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:13:17

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.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 16:03:12

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'USA-US062-2021-MRNA-1273-P301000012'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Todd'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Todd'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Simmons'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Simmons'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '9040 Friars Road Suite 540'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '9040 Friars Rd. Suite 540'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'San Diego'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'San Diego'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'CA'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'California'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '92108'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '92108'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'US'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Apr 2021 17:48:43
User entered '4'	System	29 Mar 2021 15:28:30
User entered '3'	System	19 Mar 2021 16:03:12
User entered '2'	System	19 Mar 2021 14:59:47
User entered '1'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:13:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
User entered '29/Mar/2021 11:28'	System	29 Mar 2021 15:28:30

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:13:17

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.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 15:28:30

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered	System	16 Mar 2021 13:43:16
'USA-US062-2021-MRNA-1273-P301000012'		

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Yes (Y)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'No (N)'	System	16 Mar 2021 13:43:16

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Todd'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Todd'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'Simmons'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'Simmons'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '9040 Friars Road Suite 540'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '9040 Friars Rd. Suite 540'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'San Diego'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'San Diego'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered 'CA'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'California'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 23:37:30
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 15:28:21
User entered '92108'	System	19 Mar 2021 16:03:12
Un-reviewed for Safety.	System	19 Mar 2021 14:59:47
DataPoint Un-verified.	System	19 Mar 2021 14:59:47
User entered empty.	System	19 Mar 2021 14:59:47
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered '92108'	Matthew Musikanth	18 Mar 2021 16:22:19
	(b) (4)	

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:37:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 14:59:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:43:05
User entered 'US'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:13:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Apr 2021 17:48:43
User entered '4'	System	29 Mar 2021 15:28:30
User entered '3'	System	19 Mar 2021 16:03:12
User entered '2'	System	19 Mar 2021 14:59:47
User entered '1'	System	16 Mar 2021 13:43:42

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:13:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:53:07
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:15
User entered '14/Apr/2021 13:48'	System	14 Apr 2021 17:48:43

US3112043

Folder: SAE USA-US062-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:13:17

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:53:07
User signature succeeded.	Todd Simmons (b) (4)	15 Apr 2021 23:34:15
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 17:48:43